

Exhibit B

Scully, Thomas A.

May 15, 2007

Washington, DC

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<p>1 Videotaped Deposition of THOMAS A. 2 SCULLY, a witness herein, called for examination by 3 counsel for Abbott Laboratories in the above-entitled 4 matter, pursuant to subpoena, the witness being duly 5 sworn by SUSAN L. CIMINELLI, a Notary Public in and 6 for the District of Columbia, taken at the offices of 7 Jones Day, 51 Louisiana Avenue, Northwest, 8 Washington, D.C., at 8:49 a.m. on Tuesday, May 15, 9 2007, and the proceedings being taken down by 10 Stenotype by SUSAN L. CIMINELLI, CRR, RPR, and 11 transcribed under her direction. 12 13 14 15 16 17 18 19 20 21 22</p>	<p>1 APPEARANCES (continued): 2 3 On behalf of the U.S. Department of 4 Health and Human Services: 5 TROY A. BARSKY, ESQ. 6 U.S. Department of Health and Human Services 7 CMS Division 8 C2-05-23 9 7500 Security Boulevard 10 Baltimore, MD 21244-1850 11 (410) 786-8873 12 troy.barsky@hhs.gov 13 14 On behalf of the State of California: 15 NICHOLAS N. PAUL, ESQ. 16 Supervising Deputy Attorney General 17 Civil Prosecutions Unit 18 P.O. Box 85266 19 110 West A Street, #1100 20 San Diego, CA 82186 21 (619) 688-6099 22 nicholas.paul@doj.ca.gov</p>
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<p>1 APPEARANCES: 2 3 On behalf of the United States of America: 4 GEJAA T. GOBENA, ESQ. 5 JOHN K. NEAL, ESQ. 6 ANDREW MAO, ESQ. 7 U.S. Department of Justice 8 Civil Division 9 601 D Street, Northwest 10 PHB - 9028/P.O. Box 261 11 Washington, D.C. 20044 12 Gejaa.Gobena@usdoj.gov 13 (202) 307-1088 14 15 16 17 18 19 20 21 22</p>	<p>1 APPEARANCES (continued): 2 3 On behalf of the State of Alabama: 4 ROGER BATES, ESQ. 5 Hand Arendall, L.L.C. 6 1200 Park Place Tower 7 2001 Park Place North 8 Birmingham, AL 35203 9 (205) 502-0105 10 Rbates@handarendall.com 11 12 On behalf of the State of Florida: 13 MARY S. MILLER, ESQ. 14 Office of the Attorney General of Florida 15 PL-01, The Capitol 16 Tallahassee, FL 32399-1050 17 (850) 414-3600 18 Mary_Miller@oag.state.fl.us 19 20 21 22</p>

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<p style="text-align: right;">Page 394</p> <p>1 that's -- I realize no time is good for you for this, 2 but we'd certainly work with you on your schedule to 3 find the best possible time to continue. 4 MR. HAAS: I object strenuously to the use 5 of the transcript without having the opportunity to 6 cross-examine or redirect on behalf of my client. 7 There has been a number of comments made, testimony 8 made with respect to Johnson & Johnson and its 9 products. And clarification is needed. And absent 10 that opportunity, I strenuously object to his 11 testimony and will proceed accordingly. 12 BY MR. DALY: 13 Q. What's an FUL? 14 A. Federal upper payment limit. 15 Q. And do you have a working understanding of 16 when it is that an FUL is supposed to be created for 17 a drug? 18 A. I did three years ago. I'm not sure I can 19 remember exactly how it's -- how it works, but it's 20 essentially an upper payment limit for usually I 21 believe a multisource generic drug. But I can't 22 remember exactly what the rule is, but it used to be</p>	<p style="text-align: right;">Page 396</p> <p>1 Q. Right. And that that's something that CMS 2 was going to do? 3 A. Yes. 4 MR. GOBENA: Object to the form. 5 THE WITNESS: Yes. CMS had that 6 regulation in place and I think they put out a new 7 one this year as a matter of fact. 8 BY MR. DALY: 9 Q. And do you know why -- or do you know 10 whether FULs were ever created for any of the drugs 11 that the DOJ has sued Abbott for in this litigation? 12 A. I don't know. I assume so, but I don't 13 know. I mean, Vancomycin is a generic, I think. So 14 I assume there was an FUL, but I'm not familiar, I'm 15 not specifically familiar with it. 16 Q. And sodium chloride is certainly a 17 generic, right? 18 A. Yes. So I assume there is an FUL for all 19 of them. 20 Q. Well, let me represent to you that there 21 are not, and then my question would be, do you know 22 why?</p>
<p style="text-align: right;">Page 395</p> <p>1 -- 2 Q. Three or more? 3 A. Yes. I think it was 250 percent or I 4 can't -- 250 percent or whatever the, I can't 5 remember the rule. 6 Q. Do you remember what triggered the 7 creation of FULs in terms of if there are three or 8 more different drugs that are functional equivalents 9 that CMS would then prepare or create an FUL for 10 that, those three drugs? 11 MR. GOBENA: Object to the form. 12 BY MR. DALY: 13 Q. Is that -- I'm just trying to see if that 14 jogs your memory? 15 A. I just can't remember precisely how it 16 works. It's been three years. 17 Q. Well, you remember that it was something 18 to do with if there are a number of drugs that can be 19 full substitutes for each other within a basically 20 the same drug? 21 A. Yes. It's the maximum amount CMS will pay 22 for any of them.</p>	<p style="text-align: right;">Page 397</p> <p>1 MR. GOBENA: Object to the form. 2 THE WITNESS: No. I don't. I think 3 before you get off that, I should clarify, I assume 4 it's because they are infused drugs, and the FULs are 5 generally pharmacy dispensed drugs for the most part. 6 I assume that's the reason. 7 BY MR. DALY: 8 Q. Okay. But you don't know? 9 A. I don't know. 10 (Exhibit Abbott 196 was 11 marked for identification.) 12 BY MR. DALY: 13 Q. Mr. Scully, I've handed you what we've 14 marked as Exhibit Abbott 196 which is an August 10, 15 2001 memorandum to you from Michael Mangano, who is 16 the principal deputy inspector general attaching an 17 OIG report from August 2001. And did you receive a 18 copy of this memorandum from Mr. Mangano? 19 A. I don't recall, but I'm certain I did. 20 Q. In the -- this document is entitled 21 Medicaid pharmacy actual acquisition cost of brand 22 name prescription drug products, is that correct?</p>

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<p style="text-align: right;">Page 414</p> <p>1 sure I probably agreed with it.</p> <p>2 Q. Well, do you agree with it now?</p> <p>3 A. Yes.</p> <p>4 Q. If you just flip to the very end of this</p> <p>5 and maybe this will refresh your recollection, maybe</p> <p>6 it won't, but the last couple of pages are a letter</p> <p>7 from you to Janet Rehnquist. Do you see that?</p> <p>8 A. Yes.</p> <p>9 Q. And is that your signature up by the from</p> <p>10 box?</p> <p>11 A. It looks like it might be.</p> <p>12 Q. Okay. So it would appear that you got</p> <p>13 this and sent Ms. Rehnquist back a response?</p> <p>14 A. Yes. But since I probably saw 4 or 500</p> <p>15 documents a night before I went home sometimes,</p> <p>16 whether or not I read it or not is another question.</p> <p>17 But I'm sure I agree with the conclusion in there.</p> <p>18 Q. Well, in a lot of cases, you relied on</p> <p>19 your staff to prepare letters and review things and</p> <p>20 work on responsive letters with you, correct?</p> <p>21 A. Yes.</p> <p>22 Q. And when you wrote a letter such as this,</p>	<p style="text-align: right;">Page 416</p> <p>1 states for drugs. And states increasingly did that.</p> <p>2 Q. On the -- if you go back to the letter</p> <p>3 from Ms. Rehnquist to you on the second page, do you</p> <p>4 see she indicates that in the second -- in the first</p> <p>5 full paragraph, last sentence, "unlike brand name</p> <p>6 drugs where reimbursement is predominantly based on a</p> <p>7 discounted AWP, reimbursement of generic drugs can be</p> <p>8 limited by a federal upper limit amounts that are</p> <p>9 established by CMS." Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. And was it your understanding that CMS was</p> <p>12 charged with responsibility to create FULs for drugs</p> <p>13 that met the requirements of an FUL?</p> <p>14 MR. GOBENA: Object to the form.</p> <p>15 THE WITNESS: I believe so. Yeah, Larry</p> <p>16 Reed who I mentioned earlier today is the guy who did</p> <p>17 that.</p> <p>18 BY MR. DALY:</p> <p>19 Q. And is it your experience that setting an</p> <p>20 FUL for a drug that qualified to be given an FUL had</p> <p>21 the effect of reducing reimbursement for that drug?</p> <p>22 MR. GOBENA: Object to the form.</p>
<p style="text-align: right;">Page 415</p> <p>1 to Miss Rehnquist, you were speaking on behalf of</p> <p>2 CMS, correct?</p> <p>3 A. Yes.</p> <p>4 Q. In the last part of the response, in the</p> <p>5 very last page of the document, you indicate that it</p> <p>6 was your intent to follow up with the states and</p> <p>7 strongly encourage them to review their estimates of</p> <p>8 acquisition costs, do you see that?</p> <p>9 A. Yes.</p> <p>10 Q. And to follow up with them to ensure that</p> <p>11 their actions take those findings into account. Do</p> <p>12 you see that?</p> <p>13 A. Yes.</p> <p>14 Q. Did CMS in fact do that?</p> <p>15 A. I'm sure we did. I talked to many states</p> <p>16 about paying more reasonably for drugs. As I said</p> <p>17 earlier, my general approach was not to have states</p> <p>18 pay fee for service amounts for drugs, because in</p> <p>19 many cases, the political pressure was not easy to</p> <p>20 get that done. It was always more effective in my</p> <p>21 opinion to hire a third party at-risk PBM, because</p> <p>22 they are much more likely to get lower prices for</p>	<p style="text-align: right;">Page 417</p> <p>1 THE WITNESS: You know, I do not -- it was</p> <p>2 never one of my primary policy issues to get involved</p> <p>3 in the process for setting FULs, so my general</p> <p>4 recollection is it was pretty wide range and there</p> <p>5 wasn't usually a big reduction as a result of FULs.</p> <p>6 BY MR. DALY:</p> <p>7 Q. Mr. Scully, I'm going to hand you what has</p> <p>8 been marked previously as Exhibit Abbott 108, which</p> <p>9 is an OIG report relating to omission of drugs from</p> <p>10 the federal upper limit list in 2001. And I would</p> <p>11 direct your attention to the last few pages which</p> <p>12 contained the CMS response signed by you, is that</p> <p>13 correct?</p> <p>14 A. Yes. That is my signature. Yep.</p> <p>15 Q. I wanted to direct your attention to</p> <p>16 Romanette number i of the report, which is the third</p> <p>17 page in. Under the executive summary. And I want to</p> <p>18 direct your attention to the second paragraph, which</p> <p>19 talks about the requirements for when CMS is to</p> <p>20 prepare an FUL for a given group of drugs. And I</p> <p>21 just ask you to read that to yourself, and then ask</p> <p>22 you if that's consistent with your understanding of</p>

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<p style="text-align: right;">Page 418</p> <p>1 the requirements for a creation of an FUL.</p> <p>2 MR. GOBENA: Object to the form.</p> <p>3 BY MR. DALY:</p> <p>4 Q. Have you had a chance to look at that</p> <p>5 paragraph?</p> <p>6 A. Yes.</p> <p>7 Q. Is that consistent with your understanding</p> <p>8 of when CMS was to create an FUL?</p> <p>9 MR. GOBENA: Object to the form.</p> <p>10 THE WITNESS: Yes. I forgot the 150</p> <p>11 percent number, yeah, earlier.</p> <p>12 BY MR. DALY:</p> <p>13 Q. Okay. And then what you just referenced</p> <p>14 in your earlier testimony, you said maybe it was 250</p> <p>15 percent?</p> <p>16 A. CMS came out with a new rule this year</p> <p>17 that it was 250 percent of a different calculation</p> <p>18 that I can't remember exactly how it worked.</p> <p>19 Q. And in terms of when you were at CMS, the</p> <p>20 rule was 150 percent of the published price for the</p> <p>21 least costly therapeutically equivalent product plus</p> <p>22 a reasonable dispensing fee, right?</p>	<p style="text-align: right;">Page 420</p> <p>1 THE WITNESS: No. I'm not. I was</p> <p>2 minimally involved in this process as you can tell.</p> <p>3 MR. DALY: Let's do this one here, Exhibit</p> <p>4 Abbott 095.</p> <p>5 BY MR. DALY:</p> <p>6 Q. Let me hand you what's been previously</p> <p>7 marked as Exhibit Abbott 095. And this is a</p> <p>8 September 2001 OIG report relating generally to the</p> <p>9 -- what we've called the DOJAWPs. And I wanted to</p> <p>10 direct your attention to the CMS comments at the end,</p> <p>11 they are the last couple of pages. And we talked</p> <p>12 about Ruben King-Shaw. That's somebody -- he was</p> <p>13 your deputy administrator?</p> <p>14 A. Yes.</p> <p>15 Q. And he obviously prepared the response</p> <p>16 here?</p> <p>17 A. Yes.</p> <p>18 Q. And did you have any discussions with him</p> <p>19 about the technical correction that he made in the</p> <p>20 last paragraph?</p> <p>21 A. Last paragraph of his response?</p> <p>22 Q. Yes.</p>
<p style="text-align: right;">Page 419</p> <p>1 A. I believe that's right.</p> <p>2 Q. And again, did you -- you don't know why</p> <p>3 the drugs that DOJ has sued Abbott on in this case</p> <p>4 were not FULed is that correct?</p> <p>5 MR. GOBENA: Objection. Asked and</p> <p>6 answered.</p> <p>7 THE WITNESS: I don't know. I'm guessing</p> <p>8 because they were infused drugs, they were not in the</p> <p>9 calculations somehow.</p> <p>10 BY MR. DALY:</p> <p>11 Q. Is there some exception to the FUL</p> <p>12 calculation for infused drugs?</p> <p>13 A. I don't know. I don't remember.</p> <p>14 Generally, in Medicare, there is a differential</p> <p>15 between infused drugs and, you know, outpatient drugs</p> <p>16 delivered to pharmacy. And I assume maybe there is</p> <p>17 some differentiation in Medicaid I wasn't aware of.</p> <p>18 Q. But you're not aware of any exception from</p> <p>19 the requirement that CMS create an FUL for a drug</p> <p>20 that qualifies that's based on it being an infused</p> <p>21 drug, are you?</p> <p>22 MR. GOBENA: Objection to the form.</p>	<p style="text-align: right;">Page 421</p> <p>1 A. On this page or where? Oh, I see, "we</p> <p>2 appreciate the effort."</p> <p>3 Q. The very last page of the response, page 2</p> <p>4 of his letter. I'll read it.</p> <p>5 A. I see it. No. I don't recollect having a</p> <p>6 discussion with him.</p> <p>7 Q. Well, do you see that he says that the</p> <p>8 original report stated that the inflated AWP's have</p> <p>9 caused Medicare to overpay for these products. Do</p> <p>10 you see that?</p> <p>11 A. Yes.</p> <p>12 Q. And he asked that the overpayment language</p> <p>13 be removed. Do you see that?</p> <p>14 A. I'm sorry. What have I missed? I thought</p> <p>15 he was correcting it.</p> <p>16 Q. It's the second page. It's this paragraph</p> <p>17 here. Had you looked at that paragraph when I asked</p> <p>18 you those other questions, Mr. Scully?</p> <p>19 A. No. The earlier question?</p> <p>20 Q. Right.</p> <p>21 A. No. I didn't see this, but Ruben had just</p> <p>22 come from being two weeks before the Secretary of</p>

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL) MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE) CIVIL ACTION
PRICE LITIGATION) 01-CV-12257-PBS
THIS DOCUMENT RELATES TO)
U.S. ex rel. Ven-a-Care of) Judge Patti B. Saris
the Florida Keys, Inc.)
v.) Chief Magistrate
Abbott Laboratories, Inc.,) Judge Marianne B.
No. 06-CV-11337-PBS) Bowler
- - - - -

(cross captions appear on following pages)

Videotaped deposition of SUE GASTON

Volume I

Washington, D.C.

Thursday, January 24, 2008

9:00 a.m.

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<p style="text-align: right;">Page 118</p> <p>1 Baltimore meeting in 1995?</p> <p>2 MS. ALBEE: Objection, form.</p> <p>3 A. No.</p> <p>4 Q. So as far as you know, Ven-A-Care was</p> <p>5 correct that no meaningful action had been either</p> <p>6 proposed or implemented by your agency to deal with</p> <p>7 these issues?</p> <p>8 MS. MARTINEZ: Objection, form.</p> <p>9 A. I can't say that.</p> <p>10 Q. But you as you sit here today don't know</p> <p>11 of any meaningful action that had been taken?</p> <p>12 A. I personally don't know, but that doesn't</p> <p>13 mean that it didn't occur.</p> <p>14 Q. Sure. And I'm just asking for your</p> <p>15 personal knowledge as one of the two Medicaid</p> <p>16 officials that was at the meeting?</p> <p>17 MS. MARTINEZ: Objection, form.</p> <p>18 Q. Do you recall discussing the possibility</p> <p>19 of establishing federal upper limits for specific</p> <p>20 drugs that Ven-A-Care had identified there being a</p> <p>21 large difference between AWP and their cost?</p> <p>22 MS. MARTINEZ: Objection, form.</p>	<p style="text-align: right;">Page 120</p> <p>1 exploiting their ability" --</p> <p>2 A. I'm sorry. Where are you.</p> <p>3 Q. I'm at page 483?</p> <p>4 MS. MARTINEZ: It's page 5 of the letter</p> <p>5 and he's referring to the Bates label at the bottom</p> <p>6 that says 483.</p> <p>7 THE WITNESS: Thank you. Okay.</p> <p>8 Q. The first full paragraph starts with "the</p> <p>9 drug manufacturers." Are you with me?</p> <p>10 A. Uh-huh.</p> <p>11 Q. Ven-A-Care wrote "The drug manufacturers</p> <p>12 are further exploiting their ability to falsify</p> <p>13 pricing information by using their falsifications of</p> <p>14 AWP as a marketing tool." Do you have an</p> <p>15 understanding of what Ven-A-Care is saying there?</p> <p>16 MS. MARTINEZ: Objection to form.</p> <p>17 MS. ALBEE: Objection to the form.</p> <p>18 A. You're asking me to interpret this?</p> <p>19 Q. I'm asking if you have any understanding</p> <p>20 of what they're getting at there?</p> <p>21 MS. MARTINEZ: Objection, form.</p> <p>22 A. No.</p>
<p style="text-align: right;">Page 119</p> <p>1 A. No, not on those specific drugs. No.</p> <p>2 Q. Do you know why not?</p> <p>3 MS. MARTINEZ: Objection, form.</p> <p>4 A. I don't recall that being discussed.</p> <p>5 Q. Regarding Ven-A-Care's comment that "We</p> <p>6 find this fact" -- the fact that no meaningful</p> <p>7 action had been taken -- "not only disconcerting,</p> <p>8 but potentially the source of a major embarrassment</p> <p>9 to both your agency and to the administration," do</p> <p>10 you recall that being a discussion within HCFA that</p> <p>11 the Medicare and Medicaid programs paying above</p> <p>12 acquisition cost could be a major source of</p> <p>13 impairment for HCFA?</p> <p>14 MS. MARTINEZ: Objection, form.</p> <p>15 A. Do I recall a specific comment or -- is</p> <p>16 that what you're saying?</p> <p>17 Q. Generally speaking do you recall that</p> <p>18 sentiment being expressed ever?</p> <p>19 A. No, I don't.</p> <p>20 Q. I'd like to ask you to go to 483. The</p> <p>21 first full paragraph in the middle of the page</p> <p>22 states "The drug manufacturers are further</p>	<p style="text-align: right;">Page 121</p> <p>1 Q. You have no understanding of what they're</p> <p>2 saying about --</p> <p>3 A. Are you asking me what I feel this is</p> <p>4 saying?</p> <p>5 Q. Yes. Your understanding as someone who</p> <p>6 might read this letter.</p> <p>7 MS. MARTINEZ: Objection, form.</p> <p>8 A. It's saying that they're falsifying their</p> <p>9 AWP, their pricing, as a marketing tool. So, I</p> <p>10 mean, I don't know what more --</p> <p>11 Q. Do you have an understanding of how</p> <p>12 pricing information could be used as a marketing</p> <p>13 tool?</p> <p>14 MS. MARTINEZ: Objection, form.</p> <p>15 Q. Do you understand that concept?</p> <p>16 MS. MARTINEZ: Objection, form.</p> <p>17 A. Are you saying for just general sales or</p> <p>18 are you talking about for Medicare and Medicaid for</p> <p>19 reimbursement?</p> <p>20 Q. Do you think I'm talking about general</p> <p>21 sales or do you think I'm talking about pharmacy</p> <p>22 issues?</p>

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<p>1 state. 2 (Exhibit Abbott 461 was 3 marked for 4 identification.) 5 MR. TORBORG: I'm told that we have five 6 minutes left on the tape and it's within about an 7 hour. So let's go ahead and take a break here. 8 THE VIDEOGRAPHER: This is the end of 9 tape 4. Off the record at 3:17. 10 (Recess.) 11 THE VIDEOGRAPHER: This is the beginning 12 of tape 5 in the deposition of Ms. Gaston. On the 13 record at 3:43. 14 MR. TORBORG: Welcome back, Ms. Gaston. 15 THE WITNESS: Thank you. 16 MR. TORBORG: I wanted to cover 17 something, some housekeeping matters on the record 18 very quickly. I understand from Ms. Martinez that 19 there are some additional documents from Ms. 20 Gaston's files or legacy files that are yet to be 21 produced. Is that right? 22 MS. MARTINEZ: Yes.</p>	<p>1 you said from 1991 through 2003 when you were doing 2 that, correct? 3 A. Correct. 4 Q. And those three people were -- three 5 additional people were Peter Rodler, Cindy Bergin 6 and Gail Sexton? 7 A. Gail Sexton worked on the FULs after 8 2003. 9 Q. Did she have any involvement with FULs 10 prior to 2003? 11 A. No. 12 Q. What was she doing prior to 2003? 13 A. I'm not sure. She was employed by CMS 14 around that time, but I don't know exactly when she 15 started. 16 Q. And Mr. Rodler I understand was somebody 17 who had been at HCFA and the Medicaid Bureau prior 18 to you being there? 19 A. Correct. 20 Q. And then at some point he retired or 21 moved on? 22 A. Correct.</p>
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<p>1 MR. TORBORG: And those are ones that 2 you're working on currently and we intend to 3 schedule a second day with Ms. Gaston so that we can 4 go over those documents. 5 MS. MARTINEZ: I believe what you told me 6 is that you'd look at them and see if you need an 7 additional day. 8 MR. TORBORG: That's true. 9 MS. MARTINEZ: But naturally -- 10 MR. TORBORG: I will need an additional 11 day anyway. 12 MS. MARTINEZ: Okay. That's what I 13 thought. 14 MR. TORBORG: Okay. 15 BY MR. TORBORG: 16 Q. Okay. Going back to the subject of 17 federal upper limits, Ms. Gaston, I want to ask just 18 a few very general background questions about how 19 the process worked at HCFA, who was involved in what 20 aspects and things of that nature. Earlier you 21 testified or you identified three people at CMS who 22 were involved in establishing the FULs. I believe</p>	<p>1 Q. Do you know when he retired or moved on? 2 A. No. 3 Q. Can you give me a sense? Was it early 4 '90s, late '80s? 5 A. I'm guessing it was in the '90s. Not in 6 the late '90s, but I'm not sure. 7 Q. And Cindy Bergin, when did she work at 8 CMS on the FUL issues? 9 A. She was hired -- I'm not sure exactly the 10 date -- probably eight or nine years ago. And I 11 mentored here on the FULs until I left in 2003. 12 Q. So she would have been someone that was 13 working on FUL issues starting in the mid to late 14 '90s; is that fair to say? 15 A. That's fair to say. 16 Q. And did you work with Mr. Rodler on the 17 federal upper limit issues or did you sort of 18 succeed his duties? 19 A. He taught me how to handle the federal 20 upper limit program. And then when he left I took 21 it over. 22 Q. And did Cindy Bergin take it over from</p>

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<p style="text-align: right;">Page 226</p> <p>1 you --</p> <p>2 A. Yes.</p> <p>3 Q. And then at some point is it your</p> <p>4 understanding that Gail Sexton took it over from</p> <p>5 Cindy Bergin or were they both working on it?</p> <p>6 A. She -- Cindy trained Gail and then Gail</p> <p>7 took it over when Cindy left the area.</p> <p>8 Q. So it sounds to me -- and please tell me</p> <p>9 if I'm mischaracterizing this or misunderstanding</p> <p>10 this -- that the mechanics of the FUL program were</p> <p>11 handled primarily by one person, but there was some</p> <p>12 overlap in training. Is that right?</p> <p>13 MS. MARTINEZ: Objection, form.</p> <p>14 A. Generally speaking. There were periods</p> <p>15 when it was just one person. And then when there</p> <p>16 were two, even though one was training they were</p> <p>17 both working on it.</p> <p>18 Q. And did you first get involved -- is it</p> <p>19 your recollection that a transition between yourself</p> <p>20 and Mr. Rodler happened in the early '90s; is that</p> <p>21 fair to say?</p> <p>22 A. When Pete retired then I took it over.</p>	<p style="text-align: right;">Page 228</p> <p>1 Q. Was that the same position that you had?</p> <p>2 A. Yes.</p> <p>3 Q. So you were equals, so to speak?</p> <p>4 A. Most of the analysts in our area are all</p> <p>5 health insurance specialists.</p> <p>6 Q. Okay. And you indicated that Mr. Reed</p> <p>7 would have some input into the FULs and I think you</p> <p>8 used the word even the final say.</p> <p>9 A. Correct.</p> <p>10 Q. What does that mean?</p> <p>11 A. He's the division director.</p> <p>12 Q. So what would the extent of his</p> <p>13 involvement be with FULs? When would he get</p> <p>14 involved?</p> <p>15 A. Throughout -- whenever necessary he was</p> <p>16 there to discuss issues that might need to be</p> <p>17 discussed. The final publication he was aware of</p> <p>18 and would have to give his okay in order to send it</p> <p>19 through or any letters that would go through</p> <p>20 generally were from an authority higher than me.</p> <p>21 Q. Can you tell me what kind of issues would</p> <p>22 come up in the FUL program that would necessitate</p>
<p style="text-align: right;">Page 227</p> <p>1 Q. And was there anyone else working on the</p> <p>2 FUL issues besides yourself from that point until</p> <p>3 Cindy Bergin came on in the mid to late '90s?</p> <p>4 A. There was a period of time where I</p> <p>5 trained Altamease Arnold, but --</p> <p>6 Q. Was she in your office?</p> <p>7 A. She was in our office. But she was</p> <p>8 never -- she never really worked on the program per</p> <p>9 se.</p> <p>10 Q. When you say per se, what do you mean by</p> <p>11 that? Officially or what does that mean?</p> <p>12 A. She never really learned the program to</p> <p>13 work on it.</p> <p>14 Q. What does it mean to learn the program?</p> <p>15 A. When you try to teach someone the program</p> <p>16 but they choose not to absorb what you're teaching.</p> <p>17 Q. Got it. Is she still working at CMS?</p> <p>18 A. No.</p> <p>19 Q. When did she leave CMS?</p> <p>20 A. She retired last year.</p> <p>21 Q. What was her position at CMS?</p> <p>22 A. Health insurance specialist.</p>	<p style="text-align: right;">Page 229</p> <p>1 his involvement?</p> <p>2 A. Maybe just general discussion.</p> <p>3 Especially when I was the only one working on the</p> <p>4 FUL program, just a general discussion of maybe</p> <p>5 particular drugs, the pricing just somebody to have</p> <p>6 an open discussion about how we're setting the</p> <p>7 prices, because there's manual review involved.</p> <p>8 Q. What do you mean when you say there's</p> <p>9 manual review involved? And we'll get into a little</p> <p>10 bit more the mechanics, but generally speaking what</p> <p>11 do you mean by that?</p> <p>12 A. Generally you have paper that you work</p> <p>13 from. You have the compendia with all the drug</p> <p>14 numbers on it and the pricing. And sometimes you</p> <p>15 have to make determinations if it looks like a drug</p> <p>16 is truly available or not, whether you should follow</p> <p>17 up and see if it's available. Sometimes it's better</p> <p>18 to discuss it with someone to see that you're</p> <p>19 looking at it the same way that they might be</p> <p>20 looking at it.</p> <p>21 Q. When you say truly available, do you</p> <p>22 remember is the product available from a particular</p>

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<p>1 manufacturer, whether it be because they quit making 2 the drug or they have a shortage of the drug? Is 3 that what you're talking about?</p> <p>4 A. I think what I'm talking about, at least 5 preliminarily, is we have printouts from the 6 compendia. And just looking at the printouts, 7 sometimes there might be pricing that looks like 8 it's not updated in the compendia source. So you 9 might want to discuss and say does this look like 10 it's maybe old pricing, maybe we should follow up 11 and see if it's still available. Has the pricing 12 been updated, is the drug still out there, because a 13 lot of times the compendia might not be totally up 14 to date.</p> <p>15 Q. How much of your time, if you could 16 estimate, in your position as a health insurance 17 specialist from '91 to 2003, roughly, did you spend 18 on the FUL program?</p> <p>19 A. I really can't say. There was a period 20 of time when we were trying to get a publication out 21 where I could spend the majority of my time working 22 on it. I had other duties, so the FULs couldn't</p>	<p>1 902-0446. Ms. Gaston, if you would take a look at 2 that document and let me know if that's a document 3 that you're familiar with.</p> <p>4 A. Yes. I am familiar with it.</p> <p>5 Q. Could you tell us what this document is?</p> <p>6 A. It looks like it's just an overview of 7 the federal upper limit program.</p> <p>8 Q. Did you play a part in drafting this 9 document?</p> <p>10 A. I may have. I'm not sure.</p> <p>11 Q. Ms. Gaston, can you walk me through 12 basically what you did to establish federal upper 13 limits for drugs? Can you just walk me through the 14 process?</p> <p>15 A. Do you want me to use this exhibit?</p> <p>16 Q. If it helps --</p> <p>17 A. Okay.</p> <p>18 Q. -- that would be fine. I'm just trying 19 to have you -- put me back in your office back in 20 the mid-'90s or whenever you were working on this 21 and tell me what you did.</p> <p>22 A. Well, first of all we have an</p>
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<p>1 take up all of my time every day. It just depended 2 on what activity occurred. You would stop. You 3 would work on the FULs. Then I would go back to my 4 other areas.</p> <p>5 Q. Did you work -- are you a five-day 6 employee every week or did you work part time during 7 this time?</p> <p>8 A. During the 2003 --</p> <p>9 Q. During the '91 through 2003 time period?</p> <p>10 A. I was an eight hour a day, five day --</p> <p>11 Q. Five day a week employee?</p> <p>12 A. Correct.</p> <p>13 Q. All right. Could you walk me through 14 the -- let me see if it helps facilitate the 15 discussion to find a document here that might help 16 us talk about this a bit.</p> <p>17 (Exhibit Abbott 462 was 18 marked for 19 identification.)</p> <p>20 BY MR. TORBORG:</p> <p>21 Q. For the record, what I've marked as 22 Abbott Exhibit 462 bears the Bates numbers HHC</p>	<p>1 application. I'm going to talk about it in 2 reference to the application that's used that houses 3 this information. But our systems folks when it's 4 time to set a FUL or put out a new list of FUL 5 drugs, the system folks will obtain the FDA Orange 6 Book data and they'll pull that into their system. 7 And there are some standards within that program 8 that look for the criteria that's sort of detailed 9 in this handout here.</p> <p>10 Once that criteria is met then the system 11 will pull in the latest compendia data and then 12 they'll merge the two. And the compendia data, 13 there's some criteria in there too. But they try to 14 match the compendia data to the drugs pulled from 15 the FDA. And they match them together and then the 16 application -- and I'm simplifying this -- but the 17 application will have in there FUL groups, which 18 include like all NDC numbers, and it will have the 19 FUL group, the drug names, the NDC number and then 20 the compendia and the compendia pricing in there.</p> <p>21 So it will have the source, if it's Red 22 Book, Blue Book, Medi-Span, and then it will have</p>

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<p style="text-align: right;">Page 234</p> <p>1 the prices. It will have an AWP price, a direct 2 price or WAC price. If there's not a price it'll 3 just be blank in any of those categories. And then 4 the system, the application itself -- from my 5 recollection -- it's been a while since I've used 6 it. But it will determine a FUL price where it can. 7 Then we apply some manual review just to 8 assure we have -- there's some edits and I can't 9 remember all of those. But we want to make sure 10 that it's using -- because it's supposed to use the 11 lowest price in published compendia, and we want to 12 make sure that that lowest price is a true price, 13 that it's using a true price to establish a FUL. 14 So there's a manual review that's applied 15 to some of the drugs where the pricing might not 16 look right in there or there's missing pricing. But 17 basically there's a lot of manual review that's 18 included before the final FUL listing will come out. 19 Q. Okay. I appreciate that. I'm going to 20 try to follow up on each of those steps as best I 21 can. You indicated that there was a system 22 involved.</p>	<p style="text-align: right;">Page 236</p> <p>1 CMS in the systems department that was involved in 2 this? 3 A. In the switch to the new application? 4 Q. Yeah. And basically the FUL program in 5 general. Who was involved in loading data -- 6 A. The systems support was Dona Kaufman. 7 D-o-n-a. 8 Q. Was there anyone else you recall or was 9 she the primary person? 10 A. There was someone before her, but he no 11 longer works for CMS and I can't remember his name. 12 But she was the main one for the new application. 13 Q. Do you know if she's still there today? 14 A. Yes. 15 Q. Do you recall when the new application -- 16 when you moved from the mainframe to the new 17 application? 18 A. Time? 19 Q. Yes. When that happened. 20 A. After '95. 21 Q. Prior to 1995 was the process still 22 computerized bringing in information from the</p>
<p style="text-align: right;">Page 235</p> <p>1 A. It's an application. 2 Q. I think I've seen some documents that 3 indicate the FUL process was computerized? 4 A. Correct. 5 Q. Right? Is that what you're talking about 6 when you talk about the system? 7 A. Yeah. It's an application that they use. 8 Q. And what kind of application is it? 9 A. I'm not a techie person. I don't know. 10 It's on the computer. It's an application. I don't 11 know what more -- how to describe it. 12 Q. Was the application set up before you 13 started working on it or did you -- 14 A. No. 15 Q. -- take part in setting it up? 16 A. When I first started working on FULs it 17 was in our mainframe. The activity would occur in 18 our mainframe. They took it from the mainframe and 19 put it into an application that they can use on the 20 computer, if that helps. 21 Q. And do you recall -- was there someone -- 22 you mentioned systems folks. Was there somebody at</p>	<p style="text-align: right;">Page 237</p> <p>1 compendia and that kind of information? 2 A. It was brought into the mainframe. 3 Q. Just brought into a different computer in 4 other words? I'm not a techie either. 5 A. I'm just saying mainframe because that's 6 what I know. 7 Q. And do you know what the application is 8 called? 9 A. FULs. 10 Q. FULs. Now, the Orange Book has a place 11 in this process, correct? 12 A. Right. 13 Q. And could you tell us what the Orange 14 Book is and what impact it had? 15 A. The FDA Orange Book. It lists the drugs 16 that are grouped by the FDA. If you have an Orange 17 Book available, I think they have on the front 18 page -- yeah -- the Orange Book can explain it much 19 better than I can. But -- yeah. 20 Q. I'm handing you our only copy of the 21 Orange Book. 22 A. But they get this electronically and it</p>

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<p>1 just has drugs by ingredient names. And they don't 2 have NDC numbers or anything in here. But they pull 3 data from the Orange Book where the criteria that's 4 in the regulation -- so it meets that criteria. And 5 they just pull what they can from there. There's 6 other type of system criteria in there that picks 7 the drugs that are selected for the FULs. But it 8 pulls it from the Orange Book first. 9 Q. So they have an electronic version of the 10 Orange Book? 11 A. They -- it's my understanding they do 12 now. 13 Q. Do you know when they first started using 14 an electronic version of the Orange Book versus some 15 other method of getting the Orange Book data into 16 this computer? 17 A. I really don't know. 18 Q. Do you recall at some point somebody had 19 to go through the manual copy of the Orange Book -- 20 A. Oh, no. They wouldn't go through the 21 manual. They would just request the data from FDA. 22 I think the data now is available and they could go</p>	<p>1 products approved by the FDA are A-rated which are 2 therapeutically equivalent and then there must be 3 two rated A in the Orange Book. And then there's 4 another criteria where they can also allow a B-rated 5 drug when the A-rated drug products -- when there's 6 three A-rated drug products in the Orange Book. 7 Q. Okay. So if not all the drugs within a 8 drug product group are rated A, then you have to 9 have three that are rated A? 10 A. Correct, to allow a B-rated product. 11 Q. Now, would the B-rated product or a 12 product that's not rated A, would that still be 13 governed by the FUL? 14 A. If it's included in this, yes. 15 Q. What involvement would you have in the 16 review of the Orange Book data and what gets on the 17 Orange Book lists in the computer? 18 A. I have nothing to do with that. 19 Q. Who was involved in that? 20 A. If you're saying reviewing it -- 21 Q. Just who was involved in deciding which 22 drugs from the Orange Book, whether it be manual or</p>
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<p>1 on the Web or someplace in FDA's website and obtain 2 the data now. 3 Q. But it was all done to your knowledge -- 4 as far as you can recall it was done electronically 5 in some way? 6 A. Correct. 7 Q. Somebody would set up a program that 8 would, say, identify the drugs that meet the FUL 9 criteria and then down those into a file, something 10 called Orange Book or something like that? Is that 11 how it worked? 12 A. You would have to talk to our systems 13 folks. I just know that they would get -- they had 14 the criteria set in there and however it works, you 15 know. I mean, we're simplifying it, but I'm not a 16 data person. We just tell them what we need from 17 the Orange Book and they set up their criteria on 18 how they're going to get it and how it's selected. 19 Q. And do you recall what the criteria was 20 for a drug to qualify for the FUL program? 21 A. I'm going to read it from here. But it 22 says -- well, all the formulations of the drug</p>	<p>1 electronic, get put into your FUL computer? 2 A. The system folks would download the drugs 3 from the Orange Book. If further review is needed, 4 if some of the drugs are questionable, if they met 5 the criteria and maybe weren't on there before, then 6 we would look at those drugs to verify that they did 7 meet the criteria. 8 Q. Let me ask you a specific question here. 9 And I'll give you my copy of this. 10 MR. TORBORG: And Ms. Martinez, you can 11 look on with her if you'd like. 12 MS. MARTINEZ: I'm going to try to stay 13 away from that videotape. 14 THE WITNESS: Thanks. 15 BY MR. TORBORG: 16 Q. Specifically, on this top page, the right 17 column is a drug under the prescription drug product 18 list by the name vancomycin hydrochloride. 19 MS. MARTINEZ: Give me one second just to 20 glance at what it is. 21 Counsel, would you like to lay out a 22 little bit of foundation, like maybe the date of the</p>

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<p>1 book or something?</p> <p>2 MR. TORBORG: I think it's dated on the</p> <p>3 side 1996.</p> <p>4 MS. MARTINEZ: Right. I'm just saying</p> <p>5 for the record, we're not going to have an exhibit,</p> <p>6 so --</p> <p>7 MR. TORBORG: Sure. That's a good idea.</p> <p>8 I'll do that.</p> <p>9 BY MR. TORBORG:</p> <p>10 Q. Ms. Gaston, do you recognize that book?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. Could you tell us what it is?</p> <p>13 A. It's the FDA Orange Book.</p> <p>14 Q. It's a hard copy version dated 1996?</p> <p>15 A. Correct.</p> <p>16 Q. And the FDA publishes its Orange Book</p> <p>17 once every year; is that right?</p> <p>18 A. I'm not sure.</p> <p>19 Q. Okay. In any event, this one at the side</p> <p>20 says it's 1996?</p> <p>21 A. Correct.</p> <p>22 Q. And is it your understanding that the</p>	<p>1 Q. Which manufacturers are there?</p> <p>2 MS. MARTINEZ: Excuse me. Just for the</p> <p>3 record, could we have -- again, since we have no</p> <p>4 exhibit, could we have the page that she's looking</p> <p>5 at, page number for the record?</p> <p>6 THE WITNESS: 3-302.</p> <p>7 A. Fujisawa, Lilly and I think that's it.</p> <p>8 Q. Can I take a look at that real quick?</p> <p>9 A. Mm-hmm.</p> <p>10 Q. Did you see one for Abbott?</p> <p>11 A. Oh, okay. You're over here too. It's</p> <p>12 also on page 3-303. Is this a continuation over</p> <p>13 here of this?</p> <p>14 Q. That's the way that I read it, but --</p> <p>15 MS. MARTINEZ: Since we can't see what --</p> <p>16 A. Okay. Ledderle, it looks like they're in</p> <p>17 here too. Abbott, Elkins. Okay. That's it.</p> <p>18 Q. Now, based on your understanding, are</p> <p>19 there any of those vancomycin products that are not</p> <p>20 rated A?</p> <p>21 A. It doesn't appear that way.</p> <p>22 Q. So under the regulatory and statutory</p>
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<p>1 Orange Book has different sections, one of which is</p> <p>2 titled Product Drug Cost Listing or something like</p> <p>3 that? If you look at the top page there.</p> <p>4 A. Are you talking about in here? It's been</p> <p>5 years since we've I've looked at one of these books,</p> <p>6 so --</p> <p>7 Q. If you look at the spot that I showed</p> <p>8 you, where your finger is, what does the top of that</p> <p>9 say? I can't remember exactly.</p> <p>10 A. "Prescription drug product list."</p> <p>11 Q. Do you know what that means?</p> <p>12 A. Prescription drug product list.</p> <p>13 Q. So that's a list of prescription products</p> <p>14 in the Orange Book --</p> <p>15 A. Okay.</p> <p>16 Q. -- by alphabetical order? Is that what</p> <p>17 it looks like?</p> <p>18 A. That's what it looks like.</p> <p>19 Q. And looking at vancomycin hydrochloride</p> <p>20 there, there are a number of different manufacturers</p> <p>21 listed; is that right?</p> <p>22 A. Correct.</p>	<p>1 criteria vancomycin hydrochloride would qualify as a</p> <p>2 drug product that would satisfy the FUL criteria; is</p> <p>3 that right?</p> <p>4 MR. WINGET-HERNANDEZ: Objection, form.</p> <p>5 MS. MARTINEZ: Objection, form.</p> <p>6 A. I would say no, because -- just because</p> <p>7 it's A-rated. This is an injection.</p> <p>8 Q. Okay.</p> <p>9 A. So I don't know if this product -- if</p> <p>10 this is an injectable, then there are certain</p> <p>11 products that are in the included on the FUL.</p> <p>12 Q. And we'll talk about that in a bit. Why</p> <p>13 don't we talk about it now. Why are not injectable</p> <p>14 products included on the FUL?</p> <p>15 MR. WINGET-HERNANDEZ: Objection, form.</p> <p>16 A. When I started to work on the FULs</p> <p>17 injectable products were not included. And it's my</p> <p>18 understanding that the purpose of the FUL program is</p> <p>19 to set reimbursement rates on drugs that are</p> <p>20 generally used by the Medicaid population in an</p> <p>21 outpatient-type, like a pharmacy-type setting, most</p> <p>22 commonly used products. And it's my understanding</p>

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<p style="text-align: right;">Page 246</p> <p>1 that injectables and other products many times are 2 provided in a physician's office and other type of 3 settings where they might not be claimed separately. 4 They might be included in a payment, like a 5 physician payment. 6 Also, injectables, many times when 7 they're billed on the claim form they're not -- 8 they're billed with codes rather than NDC numbers, 9 which means that the states may not be paying for 10 them through their pharmacy benefit but through 11 another means, such as a physician's visit or a 12 hospital or something like that. 13 So many times what we're trying to do 14 with the FULs is use most commonly used drugs and 15 covered outpatient drug type, so like tablets and 16 capsules. 17 Q. Is there anything in the regulations or 18 statutes that limit the FUL program to tablets or 19 capsules or other drugs that are commonly 20 administered in the outpatient setting? 21 A. Not that I know of. 22 Q. That was just the -- when you started</p>	<p style="text-align: right;">Page 248</p> <p>1 Q. Because if the initial identification of 2 drugs that satisfied the criteria was just two or 3 more A-rated drugs or three or more A-rated drugs if 4 one of them was not A-rated, and that was done by 5 computer presumably that would bring in injectable 6 drugs like vancomycin, right? 7 MS. ALBEE: Objection. 8 A. No. There are still more criteria. You 9 still have the Orange Book criteria, but there are 10 still criteria that the systems folks put in to look 11 for the type of drugs that the FUL prices are set 12 on. 13 Q. So is it your understanding that HCFA 14 specifically set up the computer program to identify 15 and exclude injectable drugs? 16 MS. MARTINEZ: Objection, form. 17 A. In one part of the process, yes. 18 Q. And do you know in what part of the 19 process that was done? 20 A. No, I don't. 21 Q. Did you have any part in that process of 22 either manually excluding the injectables drugs or</p>
<p style="text-align: right;">Page 247</p> <p>1 working on the FULs that was just the way that HCFA 2 approached it, you did not establish FULs on the 3 injectables? 4 A. Correct. 5 Q. And did you ever receive any explanation 6 about why that was? 7 A. I can't say specifically there was an 8 explanation. I think you learn this as you work 9 with the program. 10 Q. But you would agree with me that the 11 Orange Book page that I showed you does show that in 12 1996 there were at least two versions of vancomycin 13 that were rated A in the Orange Book? 14 A. Correct. 15 MS. MARTINEZ: Objection, form. 16 Q. And so -- I want to get back to this 17 computer business. Was the computer program 18 specifically designed to not include injectables or 19 how did that work? 20 A. You'd have to talk to the data folks. We 21 were not including injectables. I don't know what 22 criteria they put in there.</p>	<p style="text-align: right;">Page 249</p> <p>1 setting up a computer program such that those drugs 2 would be moved aside? 3 A. The basic criteria for the system was 4 developed before I got there. 5 Q. Who would be the best person to ask about 6 why it was that injectables were specifically 7 excluded from the FUL program? 8 MR. WINGET-HERNANDEZ: Objection, form. 9 MS. MARTINEZ: Objection, form. 10 A. I don't know. Pete Rodler was the first 11 one I know that worked on FULs. That's the only 12 person I could think of. 13 Q. Are these other -- now, we've talked a 14 little bit about Exhibit 462 that talks about the 15 Orange Book data. And we talked about the criteria 16 already, correct? And now you've identified I think 17 another criteria, which is to exclude injectable 18 drugs, right? 19 MS. MARTINEZ: Objection, form. 20 A. Correct. 21 Q. Is that criteria written down anywhere? 22 MR. WINGET-HERNANDEZ: Objection, form.</p>

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<p>1 A. I don't know.</p> <p>2 Q. Have you ever seen a policy memorandum or</p> <p>3 any other memorandum that discusses why injectables</p> <p>4 are specifically excluded from the FUL program?</p> <p>5 MS. MARTINEZ: Objection, form.</p> <p>6 A. I'm not aware of that.</p> <p>7 Q. Are you aware of any other criteria that</p> <p>8 HCFA has used to eliminate drugs that might</p> <p>9 otherwise satisfy the regulatory or statutory</p> <p>10 criteria?</p> <p>11 A. I think unit dose.</p> <p>12 Q. Can you explain a little bit -- that unit</p> <p>13 stuff always makes my head spin.</p> <p>14 A. Just the little individual unit dose</p> <p>15 packets, like little individual blister tablets that</p> <p>16 might be in the little blister pack that are</p> <p>17 generally distributed within a hospital setting.</p> <p>18 Q. And why are those -- do you understand</p> <p>19 why those are excluded?</p> <p>20 A. Here again, what I think they're trying</p> <p>21 to focus on is what's the drugs that are commonly</p> <p>22 used and dispensed by the pharmacies.</p>	<p>1 Q. Any other criteria you're aware of?</p> <p>2 A. That's all I can think of.</p> <p>3 Q. And do you know if the blister pack or</p> <p>4 the infusion bag exclusions are written down</p> <p>5 anywhere?</p> <p>6 A. I'm not aware of that.</p> <p>7 Q. Are -- I'm sorry.</p> <p>8 A. The systems folks, they might have</p> <p>9 written criteria. I really don't know and I can't</p> <p>10 speak for them. But I'm not aware of any.</p> <p>11 Q. Do you recall any discussions about --</p> <p>12 apart here today in the deposition, of course --</p> <p>13 about why infusion bags, blister packs and</p> <p>14 injectable drugs are not included in the FUL list?</p> <p>15 A. You mean specific discussions?</p> <p>16 Q. Or general discussions. Anything you</p> <p>17 recall.</p> <p>18 A. I'm sure that it was discussed over the</p> <p>19 years just within the process of working on the</p> <p>20 FULs.</p> <p>21 Q. Do you know if HCFA has since changed the</p> <p>22 way that it does FULs so that any of those three</p>
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<p>1 Q. Any other exclusion criteria that you're</p> <p>2 aware of?</p> <p>3 A. They may not want to capture the infusion</p> <p>4 bags because here again that's generally used in an</p> <p>5 inpatient setting and not dispensed at the pharmacy.</p> <p>6 Q. Do you know if that's the fact that the</p> <p>7 FUL program does not cover infusion bags? Is that</p> <p>8 something that you're aware of?</p> <p>9 A. As far as I know they don't.</p> <p>10 Q. And infusion bags would be what type of</p> <p>11 products?</p> <p>12 A. I really can't say at this point.</p> <p>13 Q. Saline solution?</p> <p>14 A. Okay, fine.</p> <p>15 Q. Is that one?</p> <p>16 A. Yeah.</p> <p>17 Q. Dextrose-type solutions?</p> <p>18 A. That's my understanding.</p> <p>19 Q. And the rationale for exclusion of those</p> <p>20 is the same as the rationale for excluding the</p> <p>21 injectable drugs?</p> <p>22 A. Correct.</p>	<p>1 categories' exclusions are no longer excluded?</p> <p>2 A. I have no idea.</p> <p>3 Q. Okay. I think that the next step you</p> <p>4 discussed was the pulling in of the compendia</p> <p>5 data --</p> <p>6 A. Correct.</p> <p>7 Q. -- into the mainframe or later the</p> <p>8 application, correct?</p> <p>9 A. Correct.</p> <p>10 Q. And was that done with electronic copies</p> <p>11 of the compendia data?</p> <p>12 A. I don't know. I don't know how they</p> <p>13 obtained that data. I would assume it's electronic,</p> <p>14 but I don't know.</p> <p>15 Q. But you did not sit down with a copy of</p> <p>16 the Red Book or the Blue Book, a manual copy, and</p> <p>17 input things into a computer?</p> <p>18 A. No.</p> <p>19 Q. Right? What you know is that by the time</p> <p>20 you got involved somebody had already loaded the</p> <p>21 data into the system?</p> <p>22 A. Correct.</p>

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<p>1 Q. Is that fair to say?</p> <p>2 A. Yup.</p> <p>3 Q. Do you know which compendia they used?</p> <p>4 A. Red Book, Blue Book and Medi-Span.</p> <p>5 Q. They Would use all three?</p> <p>6 A. Correct.</p> <p>7 Q. Do you know if they used all three from</p> <p>8 1991 when you got involved through 2003?</p> <p>9 A. I can't remember. I know there was a</p> <p>10 time when I think Medi-Span and First Databank might</p> <p>11 have merged. But I would still -- from my</p> <p>12 recollection I think there was still separate</p> <p>13 pricing under both of them. So from my recollection</p> <p>14 it was always three.</p> <p>15 Q. Did you have a hard copy of the Red Book</p> <p>16 or the Blue Book on your desk or in your cubicle?</p> <p>17 A. Red Book I would have a copy. Just</p> <p>18 their -- I think it's a monthly publication.</p> <p>19 Q. Did you have a copy of the Orange Book?</p> <p>20 A. At times.</p> <p>21 Q. And then -- so you've got the Orange Book</p> <p>22 data loaded. Is it fair to say that that's in one</p>	<p>1 were -- I can't remember exactly, but there were</p> <p>2 certain drug groups that might show up that need to</p> <p>3 be manually looked at because there might not be</p> <p>4 enough suppliers or there might not be enough</p> <p>5 pricing. And I can't remember what else might be</p> <p>6 said in there.</p> <p>7 But we would go through. And then when</p> <p>8 instances like that would occur that what we would</p> <p>9 do is sometimes print off that information and then</p> <p>10 research to see if the information in the compendia</p> <p>11 was incorrect or if it is correct then we can sort</p> <p>12 of go in there and work with what -- you know, try</p> <p>13 to make a decision whether it should be included or</p> <p>14 not.</p> <p>15 Q. How did you become aware of potential</p> <p>16 issues that may arise? Did people contact you and</p> <p>17 you looked at things in response to their concerns</p> <p>18 or was there a methodology that you followed to spot</p> <p>19 issues?</p> <p>20 MS. MARTINEZ: Objection, form.</p> <p>21 A. Are you asking me -- when you say</p> <p>22 potential issues, you mean raised by individuals</p>
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<p>1 file or one spot on the computer but then you've got</p> <p>2 the compendia data loaded in another spot?</p> <p>3 A. I can't speak for the systems aspect of</p> <p>4 it. We just -- we see it -- in the application we</p> <p>5 see the end result of the Orange Book and the</p> <p>6 compendia merged together.</p> <p>7 Q. Okay. So there's a program that merges</p> <p>8 the two together and automatically identifies drugs</p> <p>9 that meet the Orange Book criteria, any other</p> <p>10 criteria we've discussed and also have available</p> <p>11 information in the compendia data; is that right?</p> <p>12 A. Correct.</p> <p>13 Q. And that's when you get involved; is that</p> <p>14 fair to say?</p> <p>15 A. Correct.</p> <p>16 Q. You don't get involved before that?</p> <p>17 A. Correct.</p> <p>18 Q. Can you take me from that point in time</p> <p>19 through the publication of the FUL list to the</p> <p>20 public?</p> <p>21 A. From what I remember what we would do is</p> <p>22 just go through the various groups. I think there</p>	<p>1 or -- I don't know when you mean by potential</p> <p>2 issues.</p> <p>3 Q. Well, we talked about there was a manual</p> <p>4 review of this. You wouldn't just take whatever the</p> <p>5 computer spat out and make that the FUL list?</p> <p>6 A. Correct.</p> <p>7 Q. There was a manual review involved to</p> <p>8 identify some issues. I think you've talked about</p> <p>9 some of them here today. Availability of the drug,</p> <p>10 whether the pricing information was still correct.</p> <p>11 Any other issues that you recall?</p> <p>12 A. They are the two main ones, yeah.</p> <p>13 Q. How would you go about identifying those</p> <p>14 issues? Like how do you -- there's a lot of drugs</p> <p>15 on the FUL list. How would you go about figuring</p> <p>16 that stuff out?</p> <p>17 A. I can't remember exactly, because I</p> <p>18 haven't dealt with the application for years. But</p> <p>19 there was something in the application that would</p> <p>20 alert us to certain drugs that needed the manual</p> <p>21 review. Maybe it was the fact that the system</p> <p>22 couldn't come up with a price because something</p>

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<p style="text-align: right;">Page 258</p> <p>1 wasn't right in the application itself, something 2 didn't look right, so then we would have to go 3 through and verify the information that we had in 4 our system. 5 Q. The computer system that did this was all 6 housed within HCFA? 7 A. CMS. 8 Q. It's CMS. 9 A. Yes. 10 Q. And then the computer program would 11 select the lowest price of the reported prices in 12 there and then would it multiply it by 150 percent 13 and spit out a price? 14 A. Correct. 15 Q. And which prices in the compendia would 16 be included in that analysis that the computer did? 17 A. Are you saying from the compendia 18 sources? 19 Q. Yes. Average wholesale price? 20 A. Average wholesale price, direct price, 21 wholesale acquisition cost. 22 Q. Are there any other prices that you're</p>	<p style="text-align: right;">Page 260</p> <p>1 last page mean? 2 A. That was the document where it was 3 saved -- well, that I prepared it. The FME was our 4 identification. And then it has the typist and the 5 disk that the typist placed it on. 6 Q. What does FME 32 mean? 7 A. I'm not sure. 8 Q. What does the 60488 number mean? 9 A. My extension. 10 Q. Your phone number? 11 A. Yes. 12 Q. So this indicates that you were the one 13 that prepared this memorandum? 14 A. Correct. 15 Q. The second paragraph -- let me ask you 16 also, if I could, the chart at the bottom of the 17 first page of this document, that little box next to 18 file copy, what does this mean? 19 A. It's a sign-off for correspondence. 20 Q. So your name is first. That means I 21 guess you were the first one involved? Is that what 22 that means?</p>
<p style="text-align: right;">Page 259</p> <p>1 aware of? 2 A. Not that I remember. 3 Q. But the computer did all that and then 4 you came in and looked at some issues afterwards, 5 correct? 6 A. Correct. 7 MR. WINGET-HERNANDEZ: Objection, form. 8 Q. Okay. I handed you before Abbott 9 exhibit -- I forget the number of it. It was a 10 document that has a handwritten notation at the top, 11 September 15, 1993. Do you see that? 12 A. 461? 13 Q. 461, yes. 14 And I note that your name is listed at 15 the bottom of the document in a chart as well as at 16 the end of the document. There's something that 17 says at Bates page 858, FME 32, Sue Gaston, 60488. 18 A. Right. 19 Q. Let me ask you first if you remember this 20 document? 21 A. It looks familiar. 22 Q. And what does that information on the</p>	<p style="text-align: right;">Page 261</p> <p>1 A. Well, I was the one -- I prepared this, 2 the document. Larry Reed approved it. 3 Q. And then there's another name after that 4 which I can't read. 5 A. Yeah. I don't know who that is. 6 Q. And the last one is Abato. 7 A. Okay. 8 Q. Rozanne Abato; is that correct? 9 A. Correct. 10 Q. What was her position? 11 A. I don't know if we were Medicaid Bureau 12 then. But I think she was the director. And I'm 13 guessing at the title. 14 Q. The second paragraph of this document you 15 wrote "Section 1927(e)(1) and (4) of the act as 16 amended by OBRA '93 mandates that HCFA establish a 17 federal upper limit for multiple source drugs that 18 meet specific criteria." Do you see that? 19 A. Yes. 20 Q. What is the reference to the act? Is 21 that the Social Security Act? 22 A. Yes.</p>

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<p>1 Q. And OBRA '93, that would be referencing 2 what? 3 A. It's the Social Security Act. It amended 4 the Social Security Act, just like OBRA '90 5 established section 1927, OBRA '93 made amendments 6 to section 1927. 7 Q. OBRA was a statute passed by Congress? 8 A. Yes. 9 Q. Omnibus Reconciliation Act? 10 A. Correct. 11 MS. MARTINEZ: Maybe Omnibus Budget 12 Reconciliation Act? 13 MR. TORBORG: Did I not say that? 14 MS. MARTINEZ: It has OMB. 15 MR. TORBORG: Oh. I'm sorry. Omnibus 16 Budget Reconciliation Act. 17 BY MR. TORBORG: 18 Q. And was it your understanding that 19 Congress had mandated HCFA to establish federal 20 upper limits for any multiple source drugs that met 21 specific criteria? 22 MS. MARTINEZ: Objection, form.</p>	<p>1 Q. Let me explain what this document is. 2 This is a section of the Omnibus Budget 3 Reconciliation Act of 1990. And I've included a 4 cover page which has the title as well as a section 5 4401 titled Reimbursement of Prescribed Drugs. 6 That's what this is. I have not given you the 7 entire OBRA 1990. 8 I'd like you, if you would, to go eight 9 more pages from the page you're at now. I'm sorry 10 it doesn't have page numbers on this. But it would 11 be a section F, pharmacy reimbursement. Were you 12 able to find it? 13 A. Yes. 14 Q. And under section 2 it says establishment 15 of upper payment limits. Do you see that? 16 A. Yes. 17 Q. And then it says "HCFA shall establish a 18 federal upper reimbursement limit for each multiple 19 source drug for which the FDA has rated three or 20 more products therapeutically equivalent and 21 pharmaceutically equivalent, regardless of whether 22 all such additional formulations are rated as such</p>
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<p>1 Q. Right? 2 A. Correct. 3 Q. Congress had told HCFA you must do this? 4 MS. MARTINEZ: Objection, form. 5 Q. Is that right? 6 A. Congress amended the law to include this. 7 Q. But the mandates means that HCFA was 8 mandated by law to establish federal upper limits 9 for multiple source drugs that met specified 10 criteria, correct? 11 MS. MARTINEZ: Objection to form. 12 A. If that's what the legislation does, yes. 13 Q. Have you ever reviewed the legislation? 14 A. What do you mean reviewed? 15 Q. Have you looked at it? 16 A. Yes. 17 Q. The actual statute itself? 18 A. Yes. 19 (Exhibit Abbott 463 was 20 marked for 21 identification.) 22 BY MR. TORBORG:</p>	<p>1 and shall use only such formulations when 2 determining any such upper limit." Do you recall 3 reviewing this language before? 4 A. Yes. 5 Q. Now, this statutory criteria does not 6 discuss any criteria relating to injection drugs or 7 infusion drugs; is that right? 8 A. It doesn't specify any drugs in 9 particular. 10 Q. It just says "all multiple source drugs 11 for which the FDA has rated three or more products 12 therapeutically and pharmaceutically equivalent," 13 correct? 14 MR. WINGET-HERNANDEZ: Objection to form. 15 You've misread it, Counsel. 16 MR. TORBORG: I'm sorry. I'll read it 17 again. 18 BY MR. TORBORG: 19 Q. "HCFA shall establish a federal upper 20 reimbursement limit for each multiple source drug 21 for which the FDA has rated three or more products 22 therapeutically and pharmaceutically equivalent."</p>

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<p>1 Did I read that right?</p> <p>2 A. Yes, you did.</p> <p>3 Q. Now, this indicates that HCFA shall</p> <p>4 establish it for each multiple source drug. And I</p> <p>5 think we saw earlier in looking at a copy of the</p> <p>6 1996 Orange Book that for vancomycin there were</p> <p>7 three or more drugs that were therapeutically and</p> <p>8 pharmaceutically equivalent, correct?</p> <p>9 MS. MARTINEZ: Objection to form.</p> <p>10 A. Correct.</p> <p>11 Q. And you indicated that if that was an</p> <p>12 injection drug it would not have met the -- it would</p> <p>13 have been knocked out of the FUL process by the</p> <p>14 computer; is that right?</p> <p>15 A. Correct.</p> <p>16 Q. And is that consistent with the statutory</p> <p>17 language here?</p> <p>18 MR. WINGET-HERNANDEZ: Objection, form.</p> <p>19 MS. MARTINEZ: Objection, form.</p> <p>20 A. The language doesn't go into that type of</p> <p>21 detail in the statute.</p> <p>22 Q. It doesn't talk about excluding injection</p>	<p>1 end today? We've been going for I think an hour or</p> <p>2 more. I could continue to go until 5:00 if people</p> <p>3 want to stop at 5:00. And that's what I would</p> <p>4 recommend that we do, go another 25 minutes. Or</p> <p>5 since we started a little bit late, if people want</p> <p>6 to go past 5:00 I could take a break now.</p> <p>7 MR. WINGET-HERNANDEZ: I would prefer to</p> <p>8 go to 5:00 for what it's worth.</p> <p>9 MR. TORBORG: I think that probably makes</p> <p>10 more sense.</p> <p>11 MS. MARTINEZ: Yeah. I vote for going to</p> <p>12 5:00 and stopping, cutting out the break if</p> <p>13 everybody can take it.</p> <p>14 THE WITNESS: That's fine.</p> <p>15 MR. TORBORG: Is that okay?</p> <p>16 THE WITNESS: Mm-hmm.</p> <p>17 MR. TORBORG: Okay.</p> <p>18 THE VIDEOGRAPHER: I have 25 minutes</p> <p>19 remaining.</p> <p>20 MR. WINGET-HERNANDEZ: That's enough.</p> <p>21 That takes us to 5:00.</p> <p>22 MR. TORBORG: That will be perfect. All</p>
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<p>1 or infusion drugs, does it?</p> <p>2 A. No, it doesn't.</p> <p>3 Q. Do you recall any discussions about that</p> <p>4 issue while you were at HCFA, whether or not the</p> <p>5 statutory or regulations governing the federal upper</p> <p>6 limit allowed HCFA to exclude injectable or infusion</p> <p>7 drugs?</p> <p>8 A. I don't -- no. I don't remember specific</p> <p>9 discussions like that.</p> <p>10 Q. You just know that for as long as you've</p> <p>11 been working on it it's just been something that's</p> <p>12 been excluded at the outset?</p> <p>13 A. Exactly. Yes.</p> <p>14 Q. And you have some understanding of why</p> <p>15 that is, but you weren't there originally when the</p> <p>16 decision was made?</p> <p>17 A. Correct.</p> <p>18 Q. You've just been told about this</p> <p>19 rationale over time?</p> <p>20 A. Right. I understand the rationale. It's</p> <p>21 been explained to me.</p> <p>22 MR. TORBORG: What time do people want to</p>	<p>1 things are coalescing into a decision to go.</p> <p>2 MS. MARTINEZ: Counsel, could I just</p> <p>3 request that at some point you make a copy of the</p> <p>4 pages that the witness looked at in the FDA drug</p> <p>5 book and we can just --</p> <p>6 MR. TORBORG: Mark it as an exhibit</p> <p>7 maybe?</p> <p>8 MS. MARTINEZ: Well --</p> <p>9 MR. TORBORG: Let's talk about it and</p> <p>10 deal with it at the end of the deposition.</p> <p>11 MS. MARTINEZ: Yeah. But if you could</p> <p>12 PDF that or something.</p> <p>13 MR. TORBORG: Yes.</p> <p>14 BY MR. TORBORG:</p> <p>15 Q. Now, is it your understanding that the</p> <p>16 federal regulations for FULs had an aggregate test?</p> <p>17 Do you understand what I mean by that?</p> <p>18 A. I do. The test part confuses me.</p> <p>19 Q. The states' compliance with federal upper</p> <p>20 limits was measured in the aggregate, correct?</p> <p>21 A. Yes. Correct.</p> <p>22 Q. Could you explain to us as best you can</p>

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<p style="text-align: right;">Page 270</p> <p>1 in plain English what that means?</p> <p>2 A. The federal government sets prices on the</p> <p>3 federal upper limit drugs. And we release those</p> <p>4 prices to the states. The states have the</p> <p>5 flexibility to adjust those prices so that in the</p> <p>6 aggregate the same savings is achieved. So they can</p> <p>7 raise one price and lower another price. But they</p> <p>8 have to be able to validate doing that.</p> <p>9 Q. And what types of auditing does HCFA do</p> <p>10 on the states' compliance with federal upper limits?</p> <p>11 MS. MARTINEZ: Objection, form.</p> <p>12 A. I'm not familiar with CMS's auditing.</p> <p>13 Q. You don't recall yourself doing any work</p> <p>14 to see if states were actually complying with the</p> <p>15 FUL regulations; is that fair to say?</p> <p>16 A. Correct.</p> <p>17 Q. Your involvement with the FULs was to</p> <p>18 take the primary lead in getting the list published</p> <p>19 in the first instance, but not necessarily -- or not</p> <p>20 at all with dealing with whether or not the states</p> <p>21 complied with the limits?</p> <p>22 MS. MARTINEZ: Objection to form.</p>	<p style="text-align: right;">Page 272</p> <p>1 This has been done for a variety of reasons. The</p> <p>2 most prevalent reason, however, is the discovery by</p> <p>3 the FDA that a specific manufacturer of a generic</p> <p>4 drug has not been totally accurate in its</p> <p>5 formulation of the drug.</p> <p>6 "When one of these inaccurately</p> <p>7 formulated generics is discovered, HCFA is required</p> <p>8 to remove all formulations of the generic from the</p> <p>9 upper limits listing, primarily due to problems in</p> <p>10 identifying the manufacturer of any particular</p> <p>11 generic item."</p> <p>12 Do you recall this issue at all?</p> <p>13 A. No, not at all.</p> <p>14 Q. Do you recall HCFA taking steps to</p> <p>15 affirmatively remove items from the federal upper</p> <p>16 limit list?</p> <p>17 A. During the period of time that I --</p> <p>18 Q. Yes.</p> <p>19 A. We would remove drugs if they didn't meet</p> <p>20 the criteria.</p> <p>21 Q. Apart from not meeting that statutory</p> <p>22 criteria, were there other reasons why drugs were</p>
<p style="text-align: right;">Page 271</p> <p>1 A. Correct.</p> <p>2 Q. Do you know anyone that was involved in</p> <p>3 doing that?</p> <p>4 A. No.</p> <p>5 MR. TORBORG: Okay. I'd like to mark</p> <p>6 this as our next exhibit, if we could.</p> <p>7 (Exhibit Abbott 464 was</p> <p>8 marked for</p> <p>9 identification.)</p> <p>10 BY MR. TORBORG:</p> <p>11 Q. For the record, what I've marked as</p> <p>12 Abbott Exhibit 464 bears the Bates numbers</p> <p>13 NYSHD-FOIL 01682 through 83, a document dated</p> <p>14 October 2nd 1990. I ask if you'd take a look at</p> <p>15 that, Ms. Gaston, and tell me whether or not you</p> <p>16 recall it.</p> <p>17 A. No. I've never seen this before.</p> <p>18 Q. Let me ask you some questions about some</p> <p>19 language in the document to see if you can help me</p> <p>20 understand some things. The second paragraph states</p> <p>21 "Over the past year, several state operations</p> <p>22 letters have been sent to you removing upper limits.</p>	<p style="text-align: right;">Page 273</p> <p>1 removed?</p> <p>2 A. No. I'm not aware of other reasons to</p> <p>3 remove them.</p> <p>4 Q. One other -- well, were there instances</p> <p>5 where you learned that there was an availability</p> <p>6 problem with the drug?</p> <p>7 A. Correct.</p> <p>8 Q. And in those instances would a FUL be</p> <p>9 removed?</p> <p>10 A. Yes. So that maybe I should clarify.</p> <p>11 When you said statutory, also regulatory and</p> <p>12 statutory. So --</p> <p>13 Q. Another background question I had was how</p> <p>14 were drugs -- was there a code that was used to</p> <p>15 group all generic drugs of the same type and dose</p> <p>16 into one category so those can be put together for</p> <p>17 establishing a FUL?</p> <p>18 A. We had FULs -- FUL groups.</p> <p>19 Q. FUL groups?</p> <p>20 A. Yeah. That's in the application. It</p> <p>21 would be a FUL group. But I can't go into exactly</p> <p>22 what my recollection of establishing those FUL</p>

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<p style="text-align: right;">Page 274</p> <p>1 groups. But that's what we would work with on the 2 application, the FUL group, and then it would have 3 all the NDC numbers and the compendia information. 4 Q. Who established the FUL groups? 5 A. It's in the system. The system 6 establishes it. 7 Q. Is it done electronically by a computer 8 without any manual review? 9 A. The information that's pulled down from 10 the Orange Book in the compendia, once it's joined 11 together it has to be placed into a FUL group in 12 order to be into the application. Once it's in the 13 application there may be some manual review 14 required. 15 Q. But the FUL groups were set up in the 16 system and then drugs were taken from the Orange 17 Book list and the compendia list and put together 18 this FUL group list, right? 19 A. Yeah. 20 Q. And any FUL that was established for any 21 FUL group would then limit the reimbursement that 22 could be paid for any drug in that group; is that</p>	<p style="text-align: right;">Page 276</p> <p>1 recollection. 2 Q. And what is the basic criteria? 3 A. The criteria in the Orange Book that we 4 discussed earlier and the criteria in the compendia 5 for the suppliers. 6 (Exhibit Abbott 465 was 7 marked for 8 identification.) 9 BY MR. TORBORG: 10 Q. Ms. Gaston, we've marked as Abbott 11 Exhibit 465 a document bearing the Bates number HHC 12 004-0054. It appears to be an e-mail from Cindy 13 Pelter to a distribution that includes "C. Thompso," 14 which I believe is Cheryl Thompson, and an 15 organization called the American Society of Health 16 Systems Pharmacists. Do you see that? 17 A. Yes. 18 Q. If you could take a quick glance at that 19 document and tell me whether or not you recall it. 20 A. I don't recall it. 21 Q. Who was Cindy Pelter? 22 A. That's Cindy Bergin.</p>
<p style="text-align: right;">Page 275</p> <p>1 right? 2 MS. MARTINEZ: Objection, form. 3 Q. The FUL -- 4 A. It applies to a FUL group. 5 Q. Yeah. 6 A. Yes. 7 Q. Okay. 8 A. That's my recollection. 9 Q. And it may be that the FUL would apply 10 even if a particular drug was not rated A in Orange 11 Book? 12 A. As long as it met the basic criteria then 13 that FUL price would apply to all of the drugs in 14 that group. 15 Q. And the drugs in the group, would those 16 include drugs that were not rated A in Orange Book, 17 do you know? 18 A. Correct. 19 Q. It would? 20 A. It would be my understanding. As long as 21 it meets the basic criteria, then all the other 22 drugs would still be subject to the FUL. That's my</p>	<p style="text-align: right;">Page 277</p> <p>1 Q. That's Cindy Bergin? 2 A. Yes. 3 Q. That's what I suspected. That why I 4 asked you earlier if she was still named -- what's 5 her current name? 6 A. You didn't ask me if she was still -- 7 Q. It's Cindy Pelter now? 8 A. No. It's Cindy Bergin now. It's Bergin 9 now. It was Pelter when she was hired. You're 10 confusing me. This is the hardest question. 11 Q. It's been a long day. Cindy Pelter is 12 now Cindy Bergin? 13 A. Correct. 14 Q. And her name is spelled B-e-r-g-i-n? 15 A. Correct. 16 Q. I had that suspicion. And who is Cheryl 17 Thompson? Do you know her? 18 A. No. 19 Q. Do you know what the American Society of 20 Health Systems Pharmacists is? 21 A. I'm really not familiar with them, no. 22 Q. In any event, Cheryl Thompson asked</p>

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<p style="text-align: right;">Page 278</p> <p>1 Ms. Pelter a question on June 19th that was "Do the 2 prices listed in" -- this release which I won't read 3 into the record -- "reflected information recently 4 provided by First Databank." Do you see that? 5 A. Right. 6 Q. And then she responds saying "No. The 7 new federal upper limit prices do not reflect the 8 new AWP prices recently published by First Databank. 9 Those new AWP prices pertain mostly to injectable 10 drugs that are not subject to FUL prices at this 11 time. Therefore we do not need to consider the new 12 AWP's while we were compiling the new FUL list. If 13 you have any more questions please feel free to 14 e-mail me." 15 Does this refresh your recollection at 16 all about any conversations that arose within HCFA 17 or elsewhere about the fact that there were no FUL 18 prices on injectable drugs? 19 MS. MARTINEZ: Objection, form. 20 A. I could be wrong. And here again, this 21 isn't my e-mail. But what was the period of time 22 when that MFCU thing occurred?</p>	<p style="text-align: right;">Page 280</p> <p>1 identification.) 2 BY MR. TORBORG: 3 Q. For the record, what I've marked as 4 Abbott Exhibit 466 bears the Bates numbers HDD 5 006-0103 through 108. And I can represent to you, 6 Ms. Gaston, that this was a document that was pulled 7 from the OIG working paper files for their work on 8 the DOJ AWP effort, the report we looked at earlier. 9 I would ask you just to look at the first 10 page and just let me know if you've seen this. I 11 doubt you have. 12 A. (Reading.) And what was this pertaining 13 to again? 14 Q. This was a document that we found in the 15 working paper files for the OIG report concerning 16 the DOJ AWP effort? 17 MS. MARTINEZ: Objection, form. 18 A. Is this the MFCU? 19 Q. Yes. 20 A. Okay. I changed that term on you. 21 Q. That's fine. And my understanding, 22 depositing the individual who sent forth this</p>
<p style="text-align: right;">Page 279</p> <p>1 Q. I believe around 2000. 2 A. This inquiry might have come about 3 because of the MFCU issue and they were probably 4 asking this question because of that. 5 Q. And the MFCUs would have new -- they were 6 having First Databank publish new AWP's for certain 7 drugs? Is that your recollection? 8 A. Right. 9 MS. MARTINEZ: Objection, form. 10 Q. Which might impact the FULs that you were 11 setting at HCFA? 12 A. I think that's what they were asking. 13 Q. And Ms. Pelter was saying that is not 14 going to be an issue because these new AWP prices 15 pertain mostly to injectable drugs, correct? 16 A. That's what she's saying. 17 Q. Do you recall any other discussion about 18 this issue? 19 A. There may have been. I don't remember 20 any further discussion. 21 (Exhibit Abbott 466 was 22 marked for</p>	<p style="text-align: right;">Page 281</p> <p>1 document, this contains some comments that states 2 had made to OIG concerning those NAMFCU AWP's. 3 MS. MARTINEZ: Objection, form. Or 4 objection to your comment. Let me ask you, this 5 hasn't been marked as an exhibit before, then, in 6 another deposition? 7 MR. TORBORG: I think it may have been. 8 If it has, I don't have that. 9 BY MR. TORBORG: 10 Q. In any event, I want to ask you about a 11 comment that's contained in the first page, the 12 third one down, the state NC. I'm assuming it's 13 North Carolina. The second line says "At a meeting 14 about the new prices, asked Larry Reed why not put 15 these prices on a FUL. HCFA responded that they 16 couldn't do that." Do you see that? 17 A. Yes. 18 Q. Do you recall attending any meetings 19 concerning the NAMFCU AWP's? 20 MR. WINGET-HERNANDEZ: Objection, form. 21 Q. In particular between the states and 22 HCFA.</p>

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<p style="text-align: right;">Page 282</p> <p>1 MR. WINGET-HERNANDEZ: I have to object, 2 Counsel, to your manner of taking. You are using 3 this document to imply that it is notes of a meeting 4 that occurred at which this witness might have 5 attended when you know full well exactly where this 6 document came from, who produced it and the fact 7 that this witness would not have had anything to do 8 with it. It's improper for you to use the document 9 in this way. 10 MR. TORBORG: How do you know that she 11 wasn't at the meeting? 12 MR. WINGET-HERNANDEZ: You've already 13 received sworn testimony about how this information 14 was obtained from David Tawes, from the Office of 15 the Investigator General with which she has 16 absolutely no connection. 17 MR. TORBORG: Well, we established that 18 she was at the exit conference for this report. So 19 clearly she has a connection. 20 MR. WINGET-HERNANDEZ: And you 21 established in sworn testimony that this information 22 was the result of a telephone survey that was</p>	<p style="text-align: right;">Page 284</p> <p>1 discussion at that time. 2 Q. We'll do one more document quickly. This 3 will be Abbott Exhibit 467. 4 (Exhibit Abbott 467 was 5 marked for 6 identification.) 7 BY MR. TORBORG: 8 Q. For the record, what I've marked as 9 Abbott Exhibit 467 is a interrogatory response that 10 was provided by the United States in response to an 11 interrogatory issued by Abbott Laboratories. And I 12 ask you to take a look at that and let me know if 13 you are familiar with this document. 14 A. Yes, I am. 15 Q. Have you reviewed this before today? 16 A. Yes. 17 Q. Now, this document has been signed or 18 what we call in legal terminology verified by 19 someone named William Lasowski? 20 A. Yes. 21 Q. Do you know who that is? 22 A. He worked with Dennis Smith.</p>
<p style="text-align: right;">Page 283</p> <p>1 conducted by Mr. Tawes in which he was on the line 2 with a state person from North Carolina. 3 MR. TORBORG: That doesn't mean that was 4 the only meeting that discussed this issue. It's 5 clear this document suggests otherwise. 6 MR. WINGET-HERNANDEZ: I'm not objecting 7 to your question in the abstract. I'm objecting to 8 the manner in which you've used this document in 9 this instance. I think it's outrageous. 10 MR. TORBORG: Okay. 11 BY MR. TORBORG: 12 Q. Do you recall attending any meetings with 13 states concerning the NAMFCU AWP's? 14 A. I don't remember attending a meeting with 15 states on the NAMFCU. 16 Q. Do you recall any discussion of HCFA 17 stating that they could not put injectable drugs or 18 other drugs on the NAMFCU list on a FUL? 19 MS. MARTINEZ: Objection to form. 20 Q. Do you recall that being an issue of 21 discussion at any time? 22 A. No. I don't remember that being a</p>	<p style="text-align: right;">Page 285</p> <p>1 Q. How long has he been with HCFA? Do you 2 know? 3 A. I have no idea. 4 Q. Has he been there since you started? 5 A. I'm not sure. 6 Q. Do you know what his involvement has been 7 with the federal upper limit program? 8 A. I would say no involvement. Unless it 9 was prior to my time. 10 MR. TORBORG: We have one minute left on 11 the tape so why don't we go ahead and take a break 12 here and we'll adjourn at a time and place to be 13 decided later. Thank you for your time. 14 THE WITNESS: Okay. You're welcome. 15 THE VIDEOGRAPHER: This deposition 16 adjourns at 5:01 and consists of five tapes. 17 (Whereupon, at 5:01 p.m. the statement of 18 counsel was concluded.) 19 * * * * * 20 21 22</p>

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<p>1 I'll try to take a break after an hour 2 or so. But let me know if you need to take a 3 break before that. Okay? 4 A. Okay. 5 Q. Okay. Since the last time that you 6 were deposed here in this case have you been 7 deposed in any other AWP-related litigation? 8 A. No. 9 Q. Have you met with counsel for the 10 United States or CMS since your last deposition? 11 A. Yes. 12 Q. Can you tell me about that? 13 A. I met with Leslie and Jeff. Is it 14 Fauci? Last week, I think it was. 15 Q. Was that an in-person meeting? 16 A. What do you mean, in-person? 17 Q. Was it in-person? 18 A. Yes. 19 Q. And how long was the meeting? 20 A. Probably approximately two hours. 21 Q. And did you review any documents at 22 that meeting?</p>	<p>1 Q. Have you had a chance to review your 2 deposition transcript from the first day of the 3 deposition? 4 A. Yes. 5 Q. Did you notice anything that needed 6 correcting? 7 A. There were some typos, just minor 8 things that I annotated on the sheet. 9 Q. But nothing substantive that you 10 recall? 11 A. No. 12 Q. Have you discussed anyone else's 13 testimony in AWP litigation? 14 A. No. 15 Q. Do you have an idea of who else from 16 your office, state Medicaid programs or 17 otherwise, has been deposed in the case? 18 A. I understand that Larry and Deirdra and 19 Dennis Smith. 20 Q. Anyone else? 21 A. Not that I'm aware of, no. 22 Q. I'd like to mark as the next exhibit,</p>
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<p>1 A. Yes. 2 Q. Did any of those documents refresh your 3 recollection at all about the subject matters 4 contained within those documents? 5 A. Yes. 6 Q. Tell me what documents refreshed your 7 recollection. 8 A. They were sheets used when determining 9 federal upper limit prices. They were copies of 10 -- copies from the application, the federal upper 11 limit application. 12 Q. Was it your understanding that those 13 documents were being produced in AWP-related 14 litigation? 15 A. Yes. 16 Q. And that you would be asked about them? 17 That was your expectation? That's why you were 18 reviewing them, I take it? 19 A. Yes. 20 Q. Any other conversations apart from this 21 morning that you've had with counsel? 22 A. No.</p>	<p>1 which I believe will be Abbott Exhibit 752 some 2 testimony that was provided in this case by an 3 individual by the name of Zachary Bentley. This 4 is for the record a copy of the rough transcript 5 because that's what I had available to me at this 6 time. It's pages 156 through 164 of that 7 transcript. 8 (Exhibit Abbott 752 was marked for 9 identification.) 10 MS. MARTINEZ: Excuse me. Did you say 11 156? 12 MR. TORBORG: Page 256 through 264. 13 MS. MARTINEZ: Okay. 14 BY MR. TORBORG: 15 Q. Ms. Gaston, I'd like you to read to 16 yourself the line that starts from page 256 lines 17 17 through the remainder of the exhibit and then 18 I'll have some questions for you. 19 A. (Reading.) 20 MS. MARTINEZ: Just for the record, I 21 object to the use of these rough transcripts as 22 well as the attachment as an exhibit to the case,</p>

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<p style="text-align: right;">Page 316</p> <p>1 or to the deposition.</p> <p>2 MR. TORBORG: What would you have me</p> <p>3 do, Ms. Martinez? Would you like me to question</p> <p>4 about the testimony without providing her a copy</p> <p>5 of it? Would that be your preference?</p> <p>6 MS. MARTINEZ: No. I'm going to object</p> <p>7 to form either way.</p> <p>8 MR. TORBORG: Okay. But would you ask</p> <p>9 me to not show her that transcript because it's a</p> <p>10 rough form?</p> <p>11 MS. MARTINEZ: No. I'm just saying</p> <p>12 both are improper. So I'm going to object to</p> <p>13 form. The court can rule. If you want to use</p> <p>14 another approach just in case so you have the</p> <p>15 opportunity to maintain whatever answers the</p> <p>16 witness gives, you can use another approach.</p> <p>17 It's your own judgment.</p> <p>18 MR. TORBORG: Is it your position that</p> <p>19 -- would you have an objection if I showed her a</p> <p>20 final copy of the transcript?</p> <p>21 MS. MARTINEZ: Yes.</p> <p>22 MR. TORBORG: Why? I want to see if I</p>	<p style="text-align: right;">Page 318</p> <p>1 last time, but you recall an individual by the</p> <p>2 name of Zack Bentley, correct?</p> <p>3 A. Yes.</p> <p>4 Q. He's affiliated with the company called</p> <p>5 Ven-A-Care?</p> <p>6 A. Yes.</p> <p>7 Q. And for the period 1991 through 2003</p> <p>8 you were involved with the federal upper limit</p> <p>9 program for Medicaid drugs; is that right?</p> <p>10 A. Correct.</p> <p>11 Q. And you recalled attending a meeting</p> <p>12 with Ven-A-Care on or about -- you didn't</p> <p>13 remember the exact date, but on or around the</p> <p>14 date November 14th of 1995. Is that fair to say?</p> <p>15 A. I don't remember the exact date.</p> <p>16 Q. You remember having a meeting with</p> <p>17 representatives of Ven-A-Care in the mid-1990s;</p> <p>18 is that fair to say?</p> <p>19 A. Yes.</p> <p>20 Q. That was a meeting in Baltimore that</p> <p>21 was attended by a number of people, correct?</p> <p>22 A. Yes.</p>
<p style="text-align: right;">Page 317</p> <p>1 can cure whatever the objection is.</p> <p>2 MS. MARTINEZ: I just don't think it's</p> <p>3 a proper question.</p> <p>4 MR. TORBORG: It's not a proper</p> <p>5 question to ask someone about a deposition</p> <p>6 transcript?</p> <p>7 MS. MARTINEZ: I would object to the</p> <p>8 form of your question when you ask one witness</p> <p>9 about what another witness said.</p> <p>10 MR. TORBORG: You think that's</p> <p>11 improper?</p> <p>12 MS. MARTINEZ: Yeah. I would object to</p> <p>13 it.</p> <p>14 MR. TORBORG: Okay.</p> <p>15 BY MR. TORBORG:</p> <p>16 Q. You can go ahead and continue</p> <p>17 reviewing.</p> <p>18 A. Do you want me to read the whole thing?</p> <p>19 Q. Yeah. Through the end.</p> <p>20 A. Okay. (Reading.)</p> <p>21 Okay. I'm finished.</p> <p>22 Q. Ms. Gaston, I believe we covered this</p>	<p style="text-align: right;">Page 319</p> <p>1 Q. Do you recall having conversations with</p> <p>2 Mr. Bentley prior to that meeting?</p> <p>3 A. I know I had conversations with Zachary</p> <p>4 Bentley. I don't know if it was prior to the</p> <p>5 meeting, after the meeting. I don't know the</p> <p>6 time period.</p> <p>7 Q. Do you recall what the substance of</p> <p>8 those meetings was?</p> <p>9 A. The meetings or the calls?</p> <p>10 Q. I'm sorry. The calls with Mr. Bentley.</p> <p>11 Do you recall what was being discussed?</p> <p>12 A. I don't recall.</p> <p>13 Q. Do you recall Mr. Bentley advising you</p> <p>14 of -- either in a meeting that you attended or in</p> <p>15 a telephone call -- that there was a large</p> <p>16 difference between acquisition costs and AWP's for</p> <p>17 certain injectable and infusion drugs?</p> <p>18 MS. MARTINEZ: Objection, form.</p> <p>19 A. I don't remember Zachary Bentley</p> <p>20 telling me that.</p> <p>21 Q. Do you recall becoming aware of that?</p> <p>22 A. Yes.</p>

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<p>1 Q. How did you become aware of that?</p> <p>2 A. Because of the Ven-A-Care litigation.</p> <p>3 Q. And you recall becoming aware of the</p> <p>4 Ven-A-Care litigation in the mid-1990s; is that</p> <p>5 fair to say?</p> <p>6 A. Yes.</p> <p>7 Q. And you may have had conversations with</p> <p>8 Mr. Bentley or others at Ven-A-Care prior to the</p> <p>9 1995 meeting; is that fair to say?</p> <p>10 A. It's fair to say.</p> <p>11 Q. During the period in the mid-1990s --</p> <p>12 or -- I'm sorry. In the period from 1991 to,</p> <p>13 say, 1997, did you have discretion on whether or</p> <p>14 not to set a federal upper limit on drugs?</p> <p>15 MS. MARTINEZ: Objection, form.</p> <p>16 A. Yes.</p> <p>17 Q. So if you wanted to set a federal upper</p> <p>18 limit on the injectable and infusion drugs that</p> <p>19 Ven-A-Care advised you of a large difference</p> <p>20 between acquisition cost and AWP, you were able</p> <p>21 to do so; is that fair to say?</p> <p>22 MS. ALBEE: Objection, form.</p>	<p>1 what type of drugs and the criteria basically was</p> <p>2 drugs that were considered outpatient drugs,</p> <p>3 generally dispensed at the pharmacy level.</p> <p>4 Q. And we talked about this last time.</p> <p>5 But you were aware that you specifically took</p> <p>6 steps to exclude infusion and injectable drugs</p> <p>7 from the mechanism by which the FULs were</p> <p>8 calculated, correct?</p> <p>9 MS. MARTINEZ: Objection, form.</p> <p>10 A. Correct.</p> <p>11 Q. Do you recall any discussions about</p> <p>12 perhaps changing the HCFA policy or criteria not</p> <p>13 to establish FULs for injectable and infusion</p> <p>14 drugs at any point in time?</p> <p>15 A. I know that the conversation was</p> <p>16 probably discussed. I don't know when. But no</p> <p>17 steps were taken to do that.</p> <p>18 Q. Can you tell me why not steps were</p> <p>19 taken to do that?</p> <p>20 A. It's my understanding that the criteria</p> <p>21 we were using is to set federal upper limit</p> <p>22 prices on drugs that were most commonly used.</p>
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<p>1 A. No.</p> <p>2 Q. Why not?</p> <p>3 A. Because we didn't set federal upper</p> <p>4 limit prices on injectable drugs or infusion</p> <p>5 drugs. We set them on drugs that were the most</p> <p>6 commonly used such as tablets, capsules, creams.</p> <p>7 Q. But you're not aware of any written</p> <p>8 statutory or regulatory guidance that prohibited</p> <p>9 you from setting a FUL on infusion and injectable</p> <p>10 drugs; is that right?</p> <p>11 A. That's right.</p> <p>12 Q. It was a policy of HCFA at the time you</p> <p>13 started administering the FUL program not to set</p> <p>14 FULs on those drugs; is that correct?</p> <p>15 MS. MARTINEZ: Objection, form.</p> <p>16 A. I think I would rather say that it was</p> <p>17 the criteria that was established before I</p> <p>18 started doing the federal upper limit program.</p> <p>19 Q. And when you say criteria, could you</p> <p>20 explain what you mean by that?</p> <p>21 A. The criteria is how they determined</p> <p>22 what federal upper limit prices would apply to</p>	<p>1 When we stepped into the arena of injectable</p> <p>2 drugs or other drugs that weren't most commonly</p> <p>3 used, I think it was a little more difficult to</p> <p>4 capture those drugs for various reasons. So</p> <p>5 that's why we stuck with the basic criteria that</p> <p>6 we used.</p> <p>7 Q. But you believe that there were</p> <p>8 discussions about possibly moving injectable</p> <p>9 infusion drugs into the FUL program; is that fair</p> <p>10 to say?</p> <p>11 A. I wouldn't say that specifically.</p> <p>12 There could have been conversations. I wouldn't</p> <p>13 say that the conversations went as far as to say</p> <p>14 let's move them into the FUL arena. But the</p> <p>15 conversations were there. And I can only answer</p> <p>16 that generally, because I only remember short</p> <p>17 conversations maybe discussing the issue.</p> <p>18 Q. If there has been testimony from Mr.</p> <p>19 Bentley that he -- his best recollection is that</p> <p>20 he advised you of the large differences between</p> <p>21 acquisition cost and AWP for certain injectable</p> <p>22 infusion drugs at least as early as 1990, could</p>

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<p style="text-align: right;">Page 324</p> <p>1 you say that Mr. Bentley's recollection is 2 incorrect? 3 MS. ALBEE: Objection, form. 4 MS. MARTINEZ: Objection, form. 5 A. I can't answer to his statements. 6 Q. You just -- it's your testimony that 7 the conversations may have happened; you just 8 don't recall? 9 A. I don't recall conversations like that 10 with Zachary Bentley. 11 Q. But you recall conversations with Mr. 12 Bentley? 13 A. Correct. 14 Q. You just don't recall one way or the 15 other what the substance of the conversations 16 was, correct? 17 A. Correct. 18 Q. What other types of conversations would 19 you have had with Mr. Bentley apart from the 20 federal upper limit program? 21 A. I don't remember the conversations that 22 I had with Zachary Bentley. Specifically the</p>	<p style="text-align: right;">Page 326</p> <p>1 reimbursement issues. 2 Q. Do you recall Mr. Bentley ever raising 3 issues about the Medicaid drug rebate program? 4 A. I can't remember specifically what I 5 discussed with Zachary Bentley. 6 Q. Do you have any -- what is your best 7 guess about the substance of the conversations 8 that you had with Mr. Bentley and yourself? 9 MS. MARTINEZ: Objection, form. 10 Q. Do you believe it related to the FUL 11 program or something else? 12 MS. MARTINEZ: Objection, form. 13 A. My best guess would say it probably 14 related to the FUL program. 15 Q. Ms. Gaston, is it your testimony that 16 even though you became aware of the large 17 differences between acquisition costs and AWP's 18 for certain injectable and infusion products, you 19 did not believe you had the authority or 20 discretion to place FULs on those drugs? 21 MS. MARTINEZ: Objection, form. 22 Q. Is that a fair summary of your</p>
<p style="text-align: right;">Page 325</p> <p>1 conversations, I don't remember. 2 Q. And my question is a touch different. 3 A. Okay. 4 Q. And it's based on what you were doing 5 at HCFA, what your responsibilities were and your 6 knowledge of how Mr. Bentley fit into the story. 7 A. Okay. 8 Q. Do you have a sense for -- apart from 9 the federal upper limit program, what other 10 topics you would have been discussing with Mr. 11 Bentley? 12 MS. ALBEE: Objection, form. 13 MS. MARTINEZ: Objection, form. 14 A. I worked on state plan amendments. If 15 he had an issue about something that was 16 occurring in Florida or another state, he could 17 have called me about that, what was in the state 18 plan amendment. I don't even know if I was 19 handling Florida at the time. Or whatever states 20 he might have questioned. He could have asked 21 any kind of general questions about the Medicaid 22 drug rebate program or any kind of pharmacy</p>	<p style="text-align: right;">Page 327</p> <p>1 testimony? 2 MS. MARTINEZ: Objection, form. 3 A. We did not set FUL prices on those 4 types of drugs. Is it would be a matter of 5 changing the criteria. And that wouldn't be 6 strictly my place to do that. 7 Q. Okay. Fair point. Who had the 8 authority or whose place was it to change the 9 criteria? 10 A. Specifically, I don't know. I know I 11 would have to go to Larry. I don't know whether 12 he would have to get authority from someone else 13 to do that. 14 Q. And Mr. Reed was in attendance in at 15 least one of the meetings you had with Ven-A-Care 16 where they discussed the large difference between 17 acquisition cost and AWP's with Ven-A-Care, 18 correct? 19 MS. MARTINEZ: Objection, form. 20 A. He was present at the Ven-A-Care 21 meetings. 22 Q. Do you recall any steps that were taken</p>

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<p style="text-align: right;">Page 328</p> <p>1 at all to attempt to get FULs established for 2 infusion or injectable drugs? 3 A. No, I don't. 4 Q. Do you recall, Ms. Gaston, yourself 5 thinking in the mid-1990s when you were becoming 6 aware of the large differences between 7 acquisition cost and AWP for infusion and 8 injectable drugs why aren't we establishing FULs 9 for these drugs? 10 MS. MARTINEZ: Objection, form. 11 Q. Do you recall having that thought in 12 your head? 13 A. I had the thought in my head. But the 14 thought in my head is just trying to capture more 15 drugs for savings to the states. Whether it was 16 injectables or unit dose or anything outside of 17 the basic criteria, I thought about trying to 18 expand it to include additional drugs just for 19 cost saving purposes. 20 Q. Do you recall becoming aware of any 21 other classes of drugs outside of infusion and 22 injectable drugs where you were becoming aware of</p>	<p style="text-align: right;">Page 330</p> <p>1 FUL program was to mitigate against certain 2 manufacturers having high AWP's on their drugs? 3 MS. MARTINEZ: Objection, form. 4 A. The purpose of the FUL program was to 5 set a reasonable reimbursement rate for states. 6 Q. And do you have an understanding about 7 -- as the person who was in charge of the FUL 8 program from the early '90s through I think 2003, 9 2004 -- is that about -- 10 A. 2003. 11 Q. 2003. Do you have an understanding of 12 why was this program created? Why not just take 13 the AWP's for each manufacturer's drugs straight 14 from the compendia? 15 A. It was in regulations. The FUL program 16 was in regulations. 17 Q. But did you have an understanding of 18 the purpose behind it? 19 A. Yes, I did. 20 Q. And your understanding was what? 21 A. It's to set -- the federal government 22 sets a reimbursement rate for states and is</p>
<p style="text-align: right;">Page 329</p> <p>1 the large differences between acquisition cost 2 and AWP's? 3 MS. MARTINEZ: Objection, form. 4 MS. ALBEE: Objection, form. 5 A. Here again, when I'm working with the 6 FUL program I'm looking at it just to try to 7 include more drugs. I'm not looking at it -- at 8 a class of drugs and where there might be a 9 difference in the pricing. 10 Q. You testified a second ago that you 11 were concerned or you wanted to try to achieve 12 more cost savings for Medicaid, correct? 13 A. Correct. 14 Q. And the FUL program was a tool that CMS 15 could use to do that, correct? 16 A. Correct. 17 Q. And you understood the purpose of the 18 FUL program was to mitigate against certain 19 manufacturers having high AWP's, correct? 20 MS. MARTINEZ: Objection, form. 21 A. Can you repeat that? 22 Q. You understood that the purpose of the</p>	<p style="text-align: right;">Page 331</p> <p>1 trying to achieve savings. We're trying to set 2 reasonable reimbursement rates for certain 3 generic drugs. 4 Q. Do you recall taking any steps, whether 5 it be merely a conversation with Mr. Reed or 6 someone else in your office to establish federal 7 upper limits for infusion and injectable drugs? 8 A. The conversation could have come up. I 9 know it was discussed about including those in 10 FULs, but it was just a conversation. 11 Q. And the conversation, was that with Mr. 12 Reed? 13 A. I can't say. It probably included Mr. 14 Reed, because he was my supervisor. 15 Q. Who else would have been included in 16 that? 17 A. I don't know. It depends on who I was 18 mentoring at the time. 19 Q. Did you have conversations with anyone 20 outside of CMS about setting federal upper limits 21 for infusion and injectable drugs? 22 A. I don't recall that, no.</p>

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<p>1 Q. For example, to see if it triggers your</p> <p>2 memory, do you recall conversations with provider</p> <p>3 advocacy groups about whether or not to set a FUL</p> <p>4 on injectable or infusion drugs?</p> <p>5 MS. MARTINEZ: Objection, form.</p> <p>6 A. I don't remember that, no.</p> <p>7 Q. So what you recall is you believe there</p> <p>8 were conversations that would have included Mr.</p> <p>9 Reed about the possibility of putting a FUL on</p> <p>10 injectable and infusion drugs, correct?</p> <p>11 A. Correct.</p> <p>12 Q. Where did it go from there?</p> <p>13 A. It didn't go any further.</p> <p>14 Q. Do you know why not?</p> <p>15 A. I think the way that from my</p> <p>16 recollection to try to include those drugs was it</p> <p>17 was -- it was more complicated because those</p> <p>18 types of drugs aren't most commonly used</p> <p>19 generally at the pharmacy level. A lot of them</p> <p>20 aren't identified by NDC numbers. They would</p> <p>21 have J codes or HCPCS codes. So it made it much</p> <p>22 more difficult to be able to identify. And a lot</p>	<p>1 MS. ALBEE: Could you give the Bates</p> <p>2 numbers?</p> <p>3 MR. TORBORG: I do not. VAC MDL 86162</p> <p>4 through 175.</p> <p>5 BY MR. TORBORG:</p> <p>6 Q. We looked at this document last time.</p> <p>7 Do you recall that? I asked you some questions</p> <p>8 earlier.</p> <p>9 A. I can't remember.</p> <p>10 Q. Would you please go to the Bates page</p> <p>11 ending 170? This is a page titled "Generics more</p> <p>12 expensive than brand." Do you see that?</p> <p>13 A. Yes.</p> <p>14 Q. If you look down at the bottom of the</p> <p>15 first column there's J 3370 Vancocin. Do you see</p> <p>16 that?</p> <p>17 MR. WINGET-HERNANDEZ: Could you repeat</p> <p>18 the number, please?</p> <p>19 MR. TORBORG: Bates page ending 170.</p> <p>20 BY MR. TORBORG:</p> <p>21 Q. I'm making you get out another pair of</p> <p>22 glasses.</p>
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<p>1 of them, again, are not generic drugs. A lot of</p> <p>2 them are single-source drugs.</p> <p>3 So it was, I think, an area that didn't</p> <p>4 seem to work well for the federal upper limit</p> <p>5 program. And again, we go back to -- when we</p> <p>6 decide not to include something in the FULs, we</p> <p>7 still go back to the fact that the states can set</p> <p>8 reimbursement rates that they feel are</p> <p>9 reasonable.</p> <p>10 Q. Do you recall if Ven-A-Care actually</p> <p>11 supplied you with NDC numbers for certain of the</p> <p>12 injectable and infusion drugs for which they</p> <p>13 informed you of a large difference between</p> <p>14 acquisition cost and AWP's?</p> <p>15 MS. ALBEE: Objection, form.</p> <p>16 A. I can't remember that. I know that</p> <p>17 they brought materials when they met with us.</p> <p>18 But I can't remember if NDC numbers were in the</p> <p>19 materials they brought.</p> <p>20 Q. I'd like to ask you to take out Exhibit</p> <p>21 453.</p> <p>22 MS. MARTINEZ: Do you know the binder?</p>	<p>1 A. Yup.</p> <p>2 MR. WINGET-HERNANDEZ: Yeah. That's</p> <p>3 the part I was hoping you would tell us again.</p> <p>4 Why don't you say exactly what's on the page</p> <p>5 you're looking at.</p> <p>6 MR. TORBORG: The page I'm looking at?</p> <p>7 MR. WINGET-HERNANDEZ: Maybe I</p> <p>8 misunderstood you. I thought you were trying to</p> <p>9 direct our attention to a particular part of this</p> <p>10 page.</p> <p>11 MR. TORBORG: Yes. Left column below J</p> <p>12 3370.</p> <p>13 MR. WINGET-HERNANDEZ: I see. Thank</p> <p>14 you.</p> <p>15 BY MR. TORBORG:</p> <p>16 Q. Do you recall that Lilly was the brand</p> <p>17 name maker of Vancocin?</p> <p>18 A. I don't recall that.</p> <p>19 Q. And do you see that on the right-hand</p> <p>20 side of the page there's a column for generic?</p> <p>21 Do you see that?</p> <p>22 A. Correct.</p>

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<p style="text-align: right;">Page 336</p> <p>1 Q. And then below toward the bottom of the</p> <p>2 page there's a section that says "vancomycin</p> <p>3 hydrochloride." Do you see that?</p> <p>4 A. Yes.</p> <p>5 Q. And here does it appear as though Ven-</p> <p>6 A-Care has provided you with specific NDC numbers</p> <p>7 for vancomycin hydrochloride that fall under the</p> <p>8 heading of instances where generics are more</p> <p>9 expensive than brands?</p> <p>10 MS. MARTINEZ: Objection, form.</p> <p>11 A. I mean, I see NDC numbers, yes. Okay,</p> <p>12 under -- yes.</p> <p>13 Q. So is it a fair summary of your</p> <p>14 testimony -- and please tell me if it's not. I'm</p> <p>15 not trying to put words in your mouth -- that</p> <p>16 when it came to infusion and injectable drugs you</p> <p>17 knew that there was an issue with there being a</p> <p>18 large difference between acquisition cost and</p> <p>19 AWP, correct?</p> <p>20 MS. MARTINEZ: Objection, form.</p> <p>21 Q. You learned that from Ven-A-Care?</p> <p>22 MS. MARTINEZ: Objection, form.</p>	<p style="text-align: right;">Page 338</p> <p>1 generic versions.</p> <p>2 Q. Let's take apart the --</p> <p>3 A. Some of them could have HCPCS codes or</p> <p>4 J codes and they don't have NDC numbers when</p> <p>5 they're submitted on the claim form. So they're</p> <p>6 -- that complicates matters.</p> <p>7 Q. But you understand that for every drug</p> <p>8 there's an NDC number, correct?</p> <p>9 A. Correct.</p> <p>10 Q. And you knew that there were infusion</p> <p>11 and injectable drugs that were being reimbursed</p> <p>12 through Medicaid pharmacy programs, correct?</p> <p>13 MS. MARTINEZ: Objection, form.</p> <p>14 A. Correct.</p> <p>15 Q. And you knew based on your experience</p> <p>16 that generally speaking Medicaid pharmacy</p> <p>17 reimbursement was tied to NDC codes, correct?</p> <p>18 A. Correct.</p> <p>19 Q. Would it be fair to say -- strike that.</p> <p>20 I'm done with that.</p> <p>21 I'd like to hand you what we marked</p> <p>22 previously in this case as Abbott Exhibit 582.</p>
<p style="text-align: right;">Page 337</p> <p>1 MS. ALBEE: Objection, form.</p> <p>2 A. That's what they're stating, yes.</p> <p>3 Q. And you had conversation -- you believe</p> <p>4 you had conversations about moving those classes</p> <p>5 of drugs into the FUL list, correct?</p> <p>6 MS. MARTINEZ: Objection, form.</p> <p>7 A. There was conversation, yes.</p> <p>8 Q. And you didn't do so because you</p> <p>9 thought it would be too difficult?</p> <p>10 MS. MARTINEZ: Objection, form.</p> <p>11 A. I'm sure there were other reasons too.</p> <p>12 Q. What other reasons do you believe there</p> <p>13 may have been?</p> <p>14 A. I can't think of those at this time.</p> <p>15 But I'm sure that it was more than just that it's</p> <p>16 too difficult. It might not be reasonable.</p> <p>17 Q. Now, when you say might not be</p> <p>18 reasonable, can you tell me when you mean by</p> <p>19 that?</p> <p>20 A. What I mean by that is many of these</p> <p>21 drugs -- or not many, but some of these drugs</p> <p>22 could be single-source drugs, might not have</p>	<p style="text-align: right;">Page 339</p> <p>1 MR. TORBORG: Ani, this is one of those</p> <p>2 I showed Mr. Reed yesterday. So it should be in</p> <p>3 your stack.</p> <p>4 MS. MARTINEZ: Could you describe it</p> <p>5 for a second to see if -- I don't have a number</p> <p>6 on this one.</p> <p>7 MR. TORBORG: It is a document bearing</p> <p>8 the Bates number HHD 021-0121 through 22.</p> <p>9 MS. MARTINEZ: I found it. What's the</p> <p>10 exhibit number?</p> <p>11 MR. TORBORG: 582.</p> <p>12 BY MR. TORBORG:</p> <p>13 Q. Ms. Gaston, if you would take a look at</p> <p>14 that document?</p> <p>15 MR. WINGET-HERNANDEZ: Dave, is that</p> <p>16 the one you borrowed from us?</p> <p>17 MR. TORBORG: It is. Thank you for</p> <p>18 letting me borrow it.</p> <p>19 MR. WINGET-HERNANDEZ: No problem.</p> <p>20 BY MR. TORBORG:</p> <p>21 Q. For the record, this is a record of</p> <p>22 discussion dated September 27 through 28, 1995</p>

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UNITED STATES DISTRICT COURT
OF THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL : MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE : CIVIL ACTION
PRICE LITIGATION : 01-CV-12257-PBS
THIS DOCUMENT RELATES TO :
U.S. ex rel. Ven-A-Care of : Judge Patti B.
The Florida Keys, Inc., : Saris
Plaintiff, :
vs. :
ABBOTT LABORATORIES, INC., : Chief Magistrate
No. 06-CV-11337-PBS : Judge Marianne B.
Defendants. : Bowler

-----x

VOLUME II

Baltimore, Maryland

Thursday, September 27, 2007

Continued Videotape Deposition of:

LARRY REED,

the witness, was called for examination by counsel
for the Defendants, pursuant to notice, commencing

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<p style="text-align: right;">Page 590</p> <p>1 HCFA about the implications that generic drug 2 manufacturers like Abbott would face if they were 3 to lower the AWP or cause to be lowered the AWP 4 prices for their products? 5 MR. HERNANDEZ: Objection, form. 6 MS. MARTINEZ: Objection, form. 7 THE WITNESS: I think there were those 8 discussions. 9 BY MR. TORBORG: 10 Q. Tell me about those discussions. 11 MS. MARTINEZ: Objection. You may 12 answer only to the extent that it would not 13 reveal internal deliberations within HCFA that 14 preceded either a decision of HCFA or their 15 calculation of policy by HCFA. 16 THE WITNESS: Okay. My brain is really 17 slowing down, if I could just have the question 18 again. 19 (The reporter read back the 20 record.) 21 BY MR. TORBORG: 22 Q. And then tell me about those</p>	<p style="text-align: right;">Page 592</p> <p>1 that we've been -- no, I'm sure that's the right 2 one -- that we've been discussing that did 3 establish a federal upper limit program. 4 Q. I'd like to ask you to take out Exhibit 5 Abbott 108. For the record, what has been marked 6 previously as Exhibit Abbott 108 is a February 7 2004 OIG report titled "Omission of Drugs from 8 the Federal Upper Limit List in 2001." 9 Mr. Reed, my first question will be 10 whether or not you recall this document. 11 A. Yes. 12 Q. Is this a document that you reviewed? 13 A. Yes. 14 Q. Did you attend the entrance or exit 15 conference for this particular report? 16 A. I don't remember if I attended either 17 the exit or the entrance conference. 18 Q. If I could direct you to page 1 under 19 the introduction, under the section "Objective," 20 it states, "This inspection, (1), determined 21 whether drugs that met the criteria established 22 by federal laws and regulations were included on</p>
<p style="text-align: right;">Page 591</p> <p>1 discussions. 2 A. Yeah. I don't think I can go farther 3 than that in answering. 4 Q. Mr. Reed, what involvement did you have 5 with the federal upper limit program? 6 A. The federal upper limit program was in 7 our area of responsibility -- is in our area of 8 responsibility. 9 Q. And what is your understanding 10 regarding HCFA's role in implementing the federal 11 upper limit program? 12 A. Could you be more specific? 13 Q. Was HCFA directed to -- it was HCFA who 14 created the federal upper limits for particular 15 drugs; am I right? 16 MS. MARTINEZ: Objection, form. 17 THE WITNESS: Are you -- 18 BY MR. TORBORG: 19 Q. Yes. 20 A. Okay. CMS -- or, I'm sorry, at that 21 point, you're correct -- HCFA did publish a 22 regulation, a final regulation in 1987. I think</p>	<p style="text-align: right;">Page 593</p> <p>1 the federal upper limit list in 2001; and, (2), 2 calculated the potential savings that could have 3 resulted in 2001 if additional drugs that met the 4 established criteria had been included on the 5 federal upper limit list." 6 Did I read that right? 7 A. That looks correct to me. 8 Q. If I could direct you to the second 9 page under the section "Federal Upper Limit 10 List," the first paragraph references a 11 regulation established in 1987, correct? 12 A. The second page? 13 Q. Second page under the section "Federal 14 Upper Limit List." Second page of the report. 15 It's one more page after the page I just read 16 from. 17 A. I'm sorry, I'm just missing where 18 you're at. You're on the second page. I think I 19 was reading incorrectly from the first page. 20 Okay, the same sentence in two different places. 21 Sorry. 22 Q. That paragraph refers to a federal</p>

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<p>1 regulation established in 1987, does it not?</p> <p>2 A. That's correct.</p> <p>3 Q. And we looked at that Federal Register</p> <p>4 page as Exhibit Abbott 284 before; is that right?</p> <p>5 A. That's my memory, yep.</p> <p>6 Q. The second paragraph states, "In the</p> <p>7 regulation that required CMS to establish a</p> <p>8 federal upper limit amount for a drug product,</p> <p>9 (i.e., each specific dosage form and dosage</p> <p>10 amount of the drug) when, (1), all versions of a</p> <p>11 drug product have been classified as</p> <p>12 therapeutically equivalent by the Food and Drug</p> <p>13 Administration; and, (2), at least three</p> <p>14 suppliers of the drug product are listed in</p> <p>15 current editions (or updates) of published</p> <p>16 compendia of cost information for drugs available</p> <p>17 for sale nationally.</p> <p>18 The Omnibus Budget Reconciliation Act</p> <p>19 of 1990, however, changed this criteria by</p> <p>20 requiring the federal -- requiring a federal</p> <p>21 upper limit when three or more versions of a drug</p> <p>22 product have been rated therapeutically and</p>	<p>1 federal upper limit list?</p> <p>2 A. I do recall that this was the OIG</p> <p>3 finding. I don't recall what our response to</p> <p>4 that was at this point.</p> <p>5 Q. We have reviewed the federal upper</p> <p>6 limit lists that were in place from 1990 to 2000,</p> <p>7 and products that are at issue in this case are</p> <p>8 not on that federal upper limit list, sodium</p> <p>9 chloride solutions, for example, Dextrose</p> <p>10 solutions, Vancomycin, sterile water.</p> <p>11 Can you provide any insight as to why</p> <p>12 that might be?</p> <p>13 MS. MARTINEZ: Objection, form.</p> <p>14 THE WITNESS: Certain products were put</p> <p>15 on the list and certain products may not have</p> <p>16 been put on the list, so --</p> <p>17 BY MR. TORBORG:</p> <p>18 Q. And why would that be?</p> <p>19 MS. MARTINEZ: Objection, form.</p> <p>20 THE WITNESS: I believe that goes back</p> <p>21 to a time frame before I was involved with the</p> <p>22 federal upper limits program. I don't recall</p>
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<p>1 pharmaceutically equivalent by the FDA regardless</p> <p>2 of the ratings of other versions."</p> <p>3 And, Mr. Reed, is that consistent with</p> <p>4 your understanding of the regulation that was</p> <p>5 passed in 1987 as well as the statutory provision</p> <p>6 established by the OBRA of 1990?</p> <p>7 A. That looks to be generally consistent.</p> <p>8 Q. And what OIG found in this particular</p> <p>9 report was -- if you look at page ii, it would be</p> <p>10 the fourth page in the exhibit, Exhibit Abbott</p> <p>11 108, the finding was that --</p> <p>12 A. I'm sorry, could you give me that</p> <p>13 again?</p> <p>14 Q. It's the two little i's, the fourth</p> <p>15 page of the exhibit.</p> <p>16 A. Okay.</p> <p>17 Q. The finding is 90 drug products met the</p> <p>18 established criteria but were not included on the</p> <p>19 federal upper limit list in 2001.</p> <p>20 Do you recall that there were some</p> <p>21 products that met the established criteria to</p> <p>22 establish a FUL that were not included on the</p>	<p>1 what the original decision was for that, but it</p> <p>2 was continued.</p> <p>3 BY MR. TORBORG:</p> <p>4 Q. Do you know who we might ask at HCFA</p> <p>5 who could provide an answer for why it would be</p> <p>6 that products like salt water, a very commonly</p> <p>7 manufactured product, were not on the federal</p> <p>8 upper limit list?</p> <p>9 A. I think you'd have to go back to the</p> <p>10 start of the federal upper limit program. I</p> <p>11 don't know of any people still at HCFA that</p> <p>12 aren't retired that would have that information.</p> <p>13 Q. How would the process work? How would</p> <p>14 HCFA identify what products to put on the list?</p> <p>15 A. I think, as specified in here, they</p> <p>16 would have looked for -- they would look for</p> <p>17 products in the Orange Book, look for therapeutic</p> <p>18 equivalence, they would look for suppliers.</p> <p>19 Q. So if, in fact, a drug met the</p> <p>20 established criteria, a federal upper limit</p> <p>21 should have been established for that, correct?</p> <p>22 MS. MARTINEZ: Objection, form.</p>

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<p style="text-align: right;">Page 598</p> <p>1 THE WITNESS: I think I've already 2 indicated that for some drugs, we did not have a 3 federal upper limit. 4 BY MR. TORBORG: 5 Q. But I'm asking you as a matter of law 6 under the statute that I just read or summarized, 7 as summarized by OIG, if a drug product met the 8 criteria for a FUL to be established, a FUL 9 should have been established under the law; is 10 that right? 11 MS. POLLACK: Objection as to form. 12 MS. MARTINEZ: Objection, form. 13 THE WITNESS: For a federal regulation, 14 I think the wording is such that a federal 15 regulation doesn't -- an agency doesn't regulate 16 itself, and I would have to go back and look at 17 that regulation to see what latitude that allowed 18 CMS or HCFA. 19 BY MR. TORBORG: 20 Q. And do you recall that the Omnibus 21 Budget Reconciliation Act of 1990 was a statute, 22 correct?</p>	<p style="text-align: right;">Page 600</p> <p>1 Q. Okay. 2 Have you had a chance to review the 3 response? 4 A. I've looked at part of it. 5 Q. And does reviewing that allow you to 6 answer my question? 7 MS. MARTINEZ: For the record, the 8 response is three pages single-spaced. I don't 9 think the witness has had a chance to look at it. 10 MR. TORBORG: I agree. I thought he 11 looked up as though he had found what he wanted 12 to find. So -- 13 THE WITNESS: No, I wasn't aware that 14 you wanted me to do it at this point in time. 15 I don't see anything in there that 16 addresses that -- your question. 17 MR. TORBORG: We had several requests 18 to adjourn at 4:30, so why don't we do so and 19 then -- 20 MR. DRAYCOTT: Principally from the 21 witness, too, by the way. 22 MR. TORBORG: Yeah, okay. And then</p>
<p style="text-align: right;">Page 599</p> <p>1 A. Correct. 2 Q. Passed by Congress, correct? 3 A. Correct. 4 Q. Directed HCFA to establish federal 5 upper limits for products that met the criteria 6 established in that statute? 7 MR. HERNANDEZ: Objection, form. 8 THE WITNESS: Yes. 9 BY MR. TORBORG: 10 Q. Yes? 11 A. Sorry. 12 Q. And OIG found that there were some 13 drugs that met the criteria for which a FUL had 14 not been established; is that correct? 15 A. They do have drugs that they contend 16 were not listed on the federal upper limits list. 17 Q. Was it a matter of a resource 18 limitation at HCFA? Was it a matter of 19 deliberate policy choice not to establish a FUL 20 for certain drugs or something else? 21 A. I would have to go back and look at our 22 response at that point to see what we said.</p>	<p style="text-align: right;">Page 601</p> <p>1 we'll continue with Mr. Reed's deposition at a 2 mutually agreeable time and place. 3 Thank you, Mr. Reed. 4 THE WITNESS: You're welcome. 5 THE VIDEOGRAPHER: This concludes 6 Volume II of the deposition of Larry Reed. 7 Going off the record. The time is 8 16:36:36. 9 (Whereupon, signature not having 10 been waived, the deposition was adjourned at 4:36 11 p.m. to be continued at a later date and time.) 12 13 14 15 16 17 18 19 20 21 22</p>

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<p style="text-align: right;">Page 837</p> <p>1 other incentives like dispensing fees, 2 copayments, that type of thing. 3 Q. Do you know who wrote the first draft 4 of this response? 5 A. No, I don't. 6 Q. Do you know -- if you had to guess who 7 on the Medicare side of the drug payment issue, 8 who would have wrote this? Who the possible 9 candidates -- 10 A. Who the persons would be? 11 Q. Yeah. 12 A. No. Other than the people that would 13 work with part D, which would be the Centers for 14 Medicare Management, I don't know. 15 Q. Well, who are the people over there? 16 Surely you know who they are. 17 A. I know some of the people over there. 18 Q. Could you tell me who some of the 19 people are over there? 20 A. Tracy McCutcheon, Alissa Deboy, Craig 21 Minor, Judy Geisler, Cynthia Tudor. Off the top 22 of my head, that's what I remember.</p>	<p style="text-align: right;">Page 839</p> <p>1 Q. Okay. Do you know why CMS did not 2 establish federal upper limits for intravenous 3 and infusion drugs? 4 A. I think for the reasons that we 5 responded to in the interrogatory. 6 Q. Has it in your experience always been 7 the case that CMS did not have federal upper 8 limits on infusion and intravenous drugs? 9 A. In my experience, I don't remember 10 there being federal upper limits on those drugs. 11 Q. And do you know why that is? 12 A. Again, for the reasons stated in the 13 interrogatory. 14 Q. It's your testimony there wasn't, to 15 your knowledge, any specific steps taken to 16 exclude those drugs from the list of drugs that 17 would get a federal upper limit? 18 MR. WINGET-HERNANDEZ: Objection, form. 19 A. I mean, again, apart from the FULs in 20 the interrogatory, it was -- the federal upper 21 limits were what they were. 22 Q. What participation did you have in</p>
<p style="text-align: right;">Page 838</p> <p>1 Q. You indicated, Mr. Reed, that you 2 worked on an interrogatory related to the federal 3 upper limit program? 4 A. That's correct. 5 Q. And do you recall that the question 6 that Abbott asked of CMS was why there were not 7 federal upper limits established for the drugs at 8 issue in the case the United States has brought 9 against Abbott? 10 A. That's correct. 11 Q. And you reviewed that response? 12 A. I did. 13 Q. And we had the opportunity to depose 14 Ms. Gaston on issues relating to the FUL 15 program. And my takeaway from that testimony, at 16 least -- correct me if it's inconsistent with 17 your recollection -- is that CMS took steps to 18 carve out infusion and intravenous drugs from 19 getting a FUL. 20 MS. MARTINEZ: Objection to form. 21 A. I don't know what her testimony was. 22 I'm sorry.</p>	<p style="text-align: right;">Page 840</p> <p>1 deciding what drugs would get a federal upper 2 limit? 3 A. I oversaw that area. 4 Q. I'll ask you to go to Exhibit 466. 5 This is a set of comments that were prepared in 6 connection with an OIG report on the Medicaid 7 program's use of revised average wholesale 8 prices. I wanted to ask you about the comment 9 apparently -- the comment included in the row 10 titled "NC" where they commented "DOJ did not do 11 this in the right way. At a meeting about the 12 new prices ask Larry Reed why not put these 13 prices on a FUL. HCFA responded that they 14 couldn't do that." 15 Do you recall making comments on why it 16 was that HCFA did not have -- or could not put 17 FUL prices on drugs that were under investigation 18 by the Department of Justice? 19 MS. MARTINEZ: Objection, form. 20 A. And I'm sorry. When did you say this 21 occurred? 22 Q. The testimony has been about this</p>

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<p>1 document that this was prepared in connection</p> <p>2 with an OIG report that concerned new AWP prices</p> <p>3 for certain drugs that were under investigation</p> <p>4 from the Department of Justice.</p> <p>5 MS. MARTINEZ: Objection to form.</p> <p>6 A. Do you know the date of that OIG</p> <p>7 report?</p> <p>8 Q. 2001.</p> <p>9 Do you recall anyone, Mr. Reed, ever</p> <p>10 asking you why federal upper limits were not</p> <p>11 placed on intravenous and infusion drugs?</p> <p>12 A. I think you have two different</p> <p>13 questions to me. One would be if I made the</p> <p>14 statement why did I make this statement, and the</p> <p>15 second is why did we not put federal upper limits</p> <p>16 on infusion drugs.</p> <p>17 Q. Yeah. Let's take them one at a time.</p> <p>18 A. Do you want the first one, my response</p> <p>19 to this?</p> <p>20 Q. Sure.</p> <p>21 A. The federal upper limits need to be set</p> <p>22 in response to the published compendia prices.</p>	<p>1 discuss efforts that were going on in the states</p> <p>2 to increase dispensing fees in the event that</p> <p>3 average manufacturer prices would be used to set</p> <p>4 FUL prices?</p> <p>5 A. Yes.</p> <p>6 Q. What do you recall about that?</p> <p>7 A. In what regard? In regard to this</p> <p>8 document?</p> <p>9 Q. Or just generally.</p> <p>10 A. I know that they raised a number of</p> <p>11 concerns about the DRA and what the publication</p> <p>12 of AMPs would mean be for pharmacy payment.</p> <p>13 Q. Do you recall that there was a</p> <p>14 discussion that many states were considering</p> <p>15 increasing the dispensing fees if the FUL prices</p> <p>16 were lowered?</p> <p>17 A. Yes.</p> <p>18 Q. Now, in connection with your position</p> <p>19 at CMS you've worked on all matter of pharmacy</p> <p>20 issues; is that fair to say?</p> <p>21 A. I think a better statement might be</p> <p>22 that I've worked on a number of Medicaid pharmacy</p>
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<p>1 That's the requirement in the regulation. I'm</p> <p>2 not sure what these prices were. But if these</p> <p>3 were prices that were computed by the DOJ -- and</p> <p>4 again, the Bayer settlement comes to mind --</p> <p>5 these would be prices that would be not part of</p> <p>6 that system. We would then have lacked the</p> <p>7 regulatory authority to base our reimbursement --</p> <p>8 to base our federal upper limit on these prices.</p> <p>9 Q. And the second question?</p> <p>10 A. I don't know.</p> <p>11 Q. Mr. Reed, I'd ask you to go to Exhibit</p> <p>12 488, which I think would be in there.</p> <p>13 A. I think that's the next one.</p> <p>14 MR. WINGET-HERNANDEZ: 488?</p> <p>15 MR. TORBORG: 488.</p> <p>16 Q. Mr. Reed, there has been some testimony</p> <p>17 from Ms. Duzor on this document. Do you recall</p> <p>18 this particular document?</p> <p>19 MS. MARTINEZ: Objection to form.</p> <p>20 A. No. I don't recall this document.</p> <p>21 Q. Do you recall having a meeting with the</p> <p>22 National Association of Chain Drug Stores to</p>	<p>1 payment and rebate issues.</p> <p>2 Q. And you've worked extensively with your</p> <p>3 colleagues within CMS who had experience with</p> <p>4 Medicaid pharmacy issues, correct?</p> <p>5 A. I think that would be generally</p> <p>6 correct.</p> <p>7 Q. And you've worked with a number and</p> <p>8 spoken with a number of state pharmacy</p> <p>9 administrators who handled Medicaid payments for</p> <p>10 drugs, correct?</p> <p>11 A. Correct.</p> <p>12 Q. You've attended annual meetings with</p> <p>13 them, correct?</p> <p>14 A. On some occasions, correct.</p> <p>15 Q. You've attended meetings with them on</p> <p>16 the technical advisory group, correct?</p> <p>17 A. Correct.</p> <p>18 Q. You've worked with them on state plan</p> <p>19 amendments, correct?</p> <p>20 A. That's correct.</p> <p>21 Q. Have you attended phone calls or</p> <p>22 meetings with provider advocacy groups concerning</p>

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